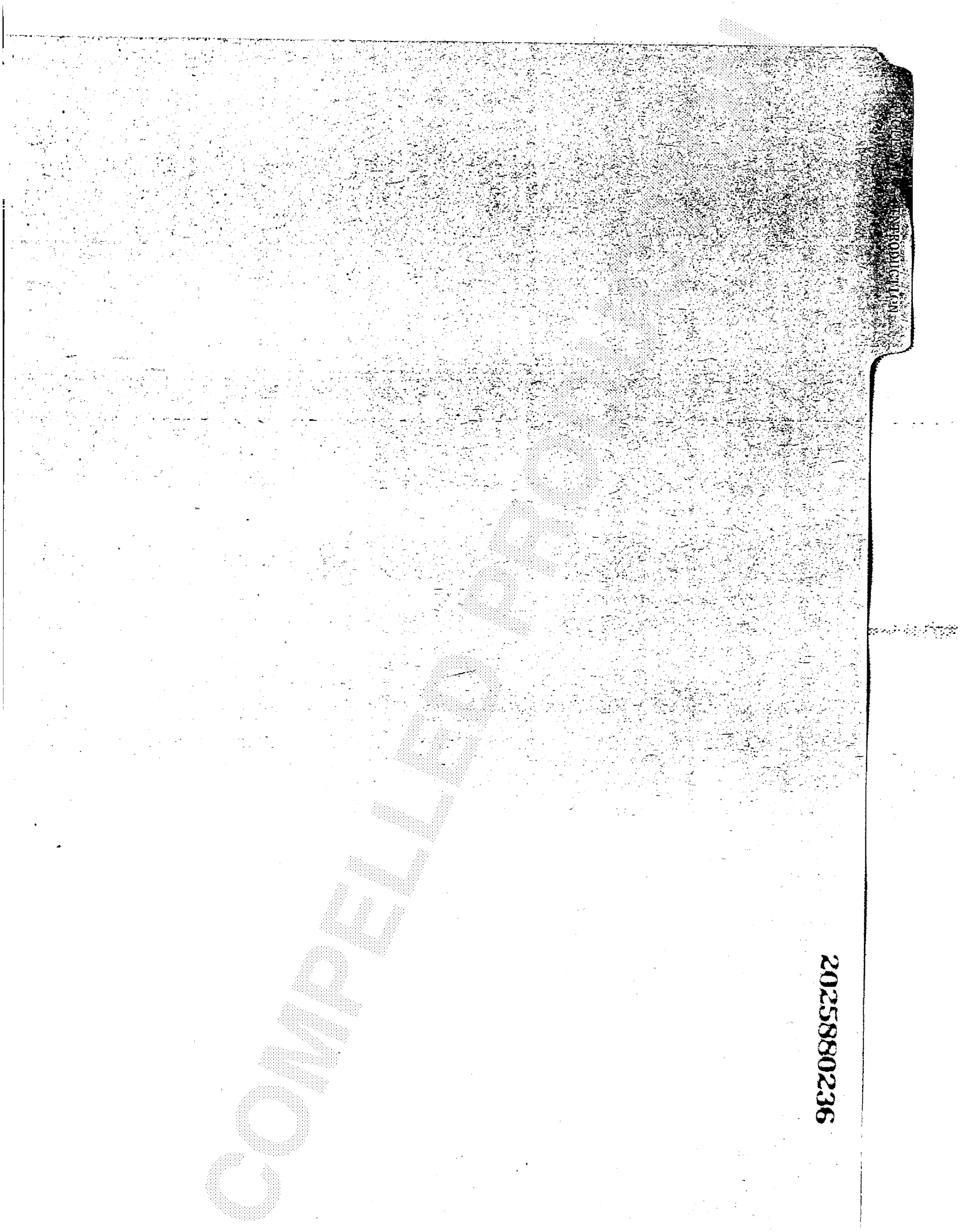
Cigarette Liability Litigation

Background and Question & Answer Book

R.J. Reynolds Tobacco Co.
September 8, 1986



Attorney Work Product*

Table of Contents

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SECTION 2 - A SMOKING AND HEALTH CHRONOLOGY

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Introduction

This binder contains background information on cigarette liability litigation and related issues. Some sections have been written in the form of questions and suggested answers because the notebook is intended for use by those whose duties might include responding to public and media inquiries.

In some instances, where an authoritative source is relevant, an extract of the pertinent part or the entire document has been included.

The questions and answers are those which have been asked in the past or which we anticipate could be asked in the future. The Q's and A's are not case specific. They are intended to address the broad issues generally present in the suits faced by R.J. Reynolds Tobacco Company and other companies in the tobacco industry.

It is not intended that the suggested answers be slavishly adhered to, but rather used as a guide in framing a response in your own words. However, departure from factual aspects of the suggested answers should only be attempted on good authority and when you are sure you're on a firm footing.

The materials in this notebook were written or compiled by James Fyock and reviewed by Harold Henderson, George Newton, Sam Witt and members of the R.J. Reynolds Tobacco Company litigation team.

In looking over these materials, should you become aware of better data, more up-to-date information or a more compelling way to express an answer, please send your suggestion to:

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CHRONOLOGY OF SMOKING AND HEALTH CONTROVERSY

1952

December: Reader's Digest article "Cancer By The Carton" by author Roy Norr appears.

1955

September: Federal Trade Commission (FTC) tells cigarette manufacturers to make no health implications in their advertising.

1957

July: Surgeon General Burney says statistics indicate that excessive cigarette smoking is a causative factor in lung cancer.

1960

January: FTC tells cigarette manufacturers to stop "tar derby" advertising and cease referring to improved health effects of filters.

1962

June: Surgeon General Terry announces formation of Advisory Committee on Smoking and Health.

1964

January: Surgeon General's advisory committee report claims cigarette smoking is causally related to lung cancer in men, is the most important cause of chronic bronchitis, may contribute to other diseases and is "a health hazard of sufficient importance in the U.S. to warrant appropriate remedial action."

Senator Maurine Neuberger (D-Ore.) introduces bill giving FTC authority to regulate cigarette advertising and labeling.

FTC begins rule making to require health warning on cigarette packages and in advertising.

June-July: House Commerce Committee has hearings on smoking and health. FTC delays its warning proposal pending Congressional action.

1965

July: Cigarette Labeling and Advertising Act enacted, that "the public may be adequately informed that cigarette smoking may be hazardous to health" and commerce may be protected against "confusing" regulations. Principal provisions:

- Cigarette packs must bear a health caution label.
- Federal and state agencies may not make labeling or advertising requirements in connection with smoking and health until at least July 1, 1969.
- FTC and the Department of Health, Education and Welfare (HEW) are to keep Congress informed on the issue through annual reports.

1966

March: FTC reverses its 1960 position by allowing tar and nicotine yields to be used in cigarette advertising. But it says there should be no implications of any health significance.

1967

June: Federal Communications Commission (FCC) rules that stations which air cigarette commercials must, under the "fairness doctrine," broadcast anti-smoking announcements.

November: FTC publishes first semi-annual measurements of tar and nicotine content of U.S. cigarettes, as requested by the Senate Commerce Committee chairman.

1969

February: FCC proposes bans on broadcast cigarette advertising.

July: Senate Commerce Consumer subcommittee hears testimony on extension of 1965 Cigarette Labeling and Advertising act. Cigarette manufacturers ask anti-trust exemption to permit inter-company agreement voluntarily to end broadcast advertising because of its unique appeal to young persons.

1970

April: President Nixon signs new Public Health Cigarette Smoking Act, an extension of the 1965 legislation. The purpose is reiterated: the public should be "adequately informed that cigarette smoking may be hazardous to health." Principal provisions:

- The law formalizes the offer of the cigarette makers to end radio-tv advertising, beginning Jan. 2, 1971.
- Package "caution" label is revised.
- States and localities may not impose on cigarette advertising or promotion "requirements or prohibitions based on smoking and health."

- FTC may not further its warning-in-advertising trade regulation proposal until at least July 1971, after which it must give Congress six months notice of any proposed further regulation.

- FTC and HEW will continue their annual reports to Congress on the smoking-health issue.

November: The new cigarette package label becomes effective: "Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health."

December: FTC accepts, by suspending rule making, an industry proposal voluntarily to display tar and nicotine yields in all cigarette advertising.

FCC announces that after cigarette commercials are off the air the "fairness doctrine" will no longer apply, that broadcasters may assume there is no more controversy about alleged ill effects. Anti-smoking announcements may be broadcast as public service announcements.

Columnists Jack Anderson reports that yet-to-be-released joint FAA-PHS study concludes tobacco smoke does not represent a health hazard to nonsmoking commercial airline passengers.

1971

January-April: New Congressional bills propose to limit or ban cigarette smoking aboard aircraft, trains, buses and passenger vessels; to ban mailing of unsolicited cigarette samples; to prohibit business tax deduction for any cigarette advertising.

FTC formally accepts tobacco industry's proposal for voluntary display of tar and nicotine content in brand advertisements.

April: Tobacco Institute announces its member companies will henceforth voluntarily display the package warning label in all print advertising.

1972

January: Major cigarette advertisers and FTC announce agreement on display of the package warning in advertisements.

February: Chairman Moss of Senate Consumer subcommittee has hearings on his 1971 proposal to regulate tar and nicotine content of cigarettes. The FAA-PHS report on smoking in aircraft is released after Sen. Cook (R-Ky.) chides Public Health Service witnesses for not making public its conclusion. The 85-page report says tobacco smoke is "judged not to represent a health hazard to the nonsmoking passengers."

September: Civil Aeronautics Board (CAB) proposes airlines voluntarily segregate smokers and nonsmokers.

1973

May: CAB orders commercial airlines to separate smokers and nonsmokers because voluntary arrangements aren't working. "The segregation of smokers, we believe, strikes an equitable balance, allowing neither smokers nor nonsmokers to infringe on the reasonable exercise of the rights of others," says CAB.

September: President Nixon signs bill prohibiting broadcast advertising of little cigars.

1975

August: Reports that FTC plans to charge cigarette companies for violating 1972 agreement to display health warnings in ads lead companies to release 62-page statement to FTC demonstrating compliance.

October: FTC receives $50,000 from PHS's National Cancer Institute (NCI) to develop means to measure carbon monoxide yields of cigarettes.

1977

July: House defeats what has become an annual effort to eliminate tobacco price support program.

October:

Internal HEW memo by Surgeon General Richmond suggests: a new Surgeon General's report on smoking and health, to be made a "media event"; a national no-smoking day; increased federal cigarette tax; a tax on cigarette advertising; increased anti-smoking advertising; ban on cigarette sales in HEW buildings; paid time off for federal workers attending stop-smoking clinics; strengthened package warning; phase-out of federal tobacco support programs, with social welfare help for small tobacco farmers.

After a year's consideration, CAB instructs staff to draft order banning cigar and pipe smoking on commercial airlines.

1978

January: HEW Secretary Califano announces "vigorous" anti-smoking campaign on 14th anniversary of the first Surgeon General's report. Included:

- A "no-smoking" policy in all HEW buildings, except in designated areas

- Asking GSA and executives of nation's top 500 companies to impose similar smoking restrictions
- Urging smoking bans on all commercial aircraft
- Asking governors of states without "clean indoor air" laws to support such legislation
- Asking insurance companies to lower rates for nonsmokers
- Directing the National Institute for Occupational Safety and Health (NIOSH) to expedite standards for restricting smoking in hazardous settings
- Ordering research on: 1) a "a less hazardous" cigarette, 2) "passive" smoking, 3) persons at high risk, 4) reasons why people smoke, 5) smoking dependence, 6) ways to overcome smoking "addiction"
- Supplanting National Clearinghouse for Smoking and Health with the Office on Smoking and Health (OSH), reporting directly to Assistant Secretary for Health
- A new Surgeon General's report on smoking and health for publication January 1979
- Strengthening the warning label, requiring tar, nicotine and carbon monoxide listings on packs and establishing maximum tar and nicotine level in cigarettes
- Asking Treasury to consider whether higher cigarette taxes would discourage smoking
- Asking broadcasters to increase time allotted for anti-smoking public service announcements.

April: New birth control pill package insert ordered by FDA warns that "cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels from oral contraceptive use."

August: Surgeon General Richmond denounces a report of NCI's Dr. Gio Gori that specific amounts of some cigarettes can be smoked "without apparent risk."

September: House subcommittee hears 18 scientists refute claims that ambient cigarette smoke is harmful to nonsmokers. Chairman Jones (D-Ga.) concludes that "if we are ever going to have a consensus on this matter, it will be scientific facts, not emotions, that lead to it."

October: House subcommittee hearing investigates FDA's requirement of a smoking warning in oral contraceptives packages. Committee Chairman Fountain (D-N.C.) concludes "the evidence upon which FDA entirely based its order is inconclusive, of questionable quality and not scientifically valid."

1979

January: HEW releases $250,000 1979 Surgeon General's report on smoking and health. The 1,200-page book, repeating most of the charges in the 1964 report, claims that smoking has been shown to be more dangerous than suspected in 1964 and that cigarettes may kill 346,000 Americans in 1979. It emphasizes and elaborates alleged social costs of smoking, high risks of smoking in certain occupational settings, link between smoking and heart disease and increased smoking by children.

Federal judge directs six cigarette manufacturers and 20 advertising agencies to turn over to FTC subpoenaed material on consumer research and advertising, 1964 to present.

HEW Secretary Califano asks chief executives of six major cigarette companies to allocate 10 percent of industry's advertising budget for special campaign "emphasizing that smoking is not for children." (In separate replies, the executives termed the suggestion "misplaced" and "counter-productive," pointed to failure of a $7 million government anti-smoking youth campaign earlier in California.)

July: HEW Secretary Califano resigns in Carter Cabinet shake-up, is replaced by Patricia Roberts Harris, former Secretary of Housing and Urban Development, who, President Carter tells a news conference, will continue HEW's anti-smoking campaign.

October-November: FTC releases "inadvertently" a confidential public opinion survey on cigarette smoking commissioned by tobacco industry and acquired under FTC subpoena. Four tobacco companies file with U.S. District Court, urging FTC be ordered to take greater care of confidential documents.

1980

July: FTC begins testing cigarettes for carbon monoxide yield. Chairman Pertschuk calls it another step in the policy of "stimulating the development of progressively less hazardous cigarettes."

December: District of Columbia Appeals Court denies petition of cigarette makers and advertising agencies, upholding FTC's "statutory authority to initiate an investigation into cigarette advertising and to issue subpoenas as part of that investigation."

1981

January: A seven-page press statement accompanying the 1981 Surgeon General's report says "lower-tar, lower-nicotine cigarettes appear to provide some small protection in the smoker assuming the absence of changes in smoking behavior." The $227,000 report, "The Health Consequences of Smoking: The Changing Cigarette," notes "a continually changing population of smokers who smoke a continually changing cigarette in a continually changing manner."

February: C. Everett Koop, chief surgeon at Children's Hospital, Philadelphia, is nominated the nation's 13th Surgeon General. Controversy over his anti-abortion stand will delay confirmation for nine months.

1982

January: Despite rumors of cigarette tax increase proposals, President Reagan in State of Union message says no to higher excise taxes, declaring "I will not ask (the Congress) to try to balance the budget on the backs of the American taxpayers."

Bills are introduced in Congress to raise the cigarette excise to balance the budget, to fund Medicare and for other purposes.

National Academy of Sciences report, "Outlook for Science and Technology," says "The decline in the (cardiovascular) death rate started well before the campaign advocating preventive measures had taken hold in the U.S.; the number of people who continue to smoke heavily (two packs a day or more) appears not to have declined."

March: CSOH presents three celebrity witnesses at first day of hearings of Waxman's House Commerce Health and the Environment subcommittee on Comprehensive Smoking Prevention Education Act. Bill calls for rotating warnings to mention "addiction," lung cancer, heart disease, emphysema and pregnancy. AHA witness calls current warning "overexposed" and "worn out." Subcommittee member Bliley (R-Va.) emphasizes no research exists showing new warnings will cut consumption.

At day two of Waxman's Health subcommittee hearings, Asst. Health Secretary Brandt endorses concept of "stronger" and multiple labels but offers different rotation scheme to "minimize industry expense." Brandt opposes creation of statutory Office of Smoking and Health.

Day three of Waxman hearings is devoted to tobacco industry witnesses. TI Exec. Comm. Chairman Horrigan likens proposed new labels to "little textbooks." Behavioral experts say current label is working well. Health experts and others testify the bill's scientific "findings" are based on insufficient data, could divert attention and resources from crucially needed research on chronic diseases. Pollster Roper submits data which indicate "public is highly aware of the reported dangers of smoking."

Hatch's Senate Labor and Human Resources Committee tackles Comprehensive Smoking Prevention Education Act of 1982. HHS Asst. Secretary Brandt testifies that although Administration supports stronger health warnings, "specific wording" and ways they may be used is "still being studied." National Institute on Drug Abuse director terms cigarette smoking "most widespread example of drug dependence in this country." TI's Horrigan calls current warning "very effective," expresses concern over provisions calling for disclosure of cigarette additives.

Senate approves doubling federal cigarette excise to 16 cents a pack as part of budget-balancing measure described by Washington Post as apparently the largest tax increase since World War II.

August: Federal cigarette tax will double, to 16 cents per pack, Jan. 1 as part of $98.3 billion dollar tax bill approved by Congress. Bipartisan group of 18 congressmen says it will sue, claiming revenue measure is unconstitutional because it originated in Senate, not House.

September: Results are reported on Multiple Risk Factor Intervention Trial (MRFIT), 10-year, $115 million NHLBI project examining smoking, blood pressure and cholesterol levels in middle-age men. It finds no significant difference in death rates between group receiving medical treatment, including quit-smoking advice, and "usual care" group.

1983

January: Federal excise tax on cigarettes is doubled from 8 to 16. Due to sunset October 1985.

1984

January: R.J. Reynolds begins Public Issues campaign.

1985

April: A Wall Street Journal story by Ed Bean calls the public's attention to a "new wave" of lawsuits against tobacco companies.

October: New rotating warnings go into effect.

November-December: Galbraith v. R.J. Reynolds Tobacco Co. and Roysdon v. R.J. Reynolds Tobacco Co. tried in California and Tennessee. Galbraith results in a 9-3 jury verdict in favor of RJR. Judge Hull directed a verdict in favor of R.J. Reynolds Tobacco Company in Roysdon. Judge Hull ruled that warnings on cigarette packs are adequate as a matter of law and that plaintiffs had failed to prove that cigarettes were "unreasonably dangerous."

December: 320 cross-complaints by GAF corporations against tobacco companies dismissed without prejudice in 3 California state courts. Browner v. R.J. Reynolds Tobacco Company (occupational exposure case) voluntarily dismissed.

1986

January: Plaintiff's attorney in Roysdon appeals Judge Hull's ruling on preemption to the U.S. Court of Appeals for the Sixth Circuit.

March: The U.S. Court of Appeals for the Third Circuit affirms the magistrate's protective order in Cipollone.

April: The U.S. Court of Appeals for the Third Circuit reverses the order of the U.S. District Court for the District of New Jersey on the question of preemption. The ruling holds that the health warnings on cigarette packs prescribed by The Federal Cigarette Labeling and Advertising Act are adequate as a matter of law.

Judge David Mazzone (U.S. District Court, District of Massachusetts) denies Liggett's motion to dismiss Palmer v. Liggett on grounds of preemption. Question of preemption certified to the U.S. Court of Appeals for the First Circuit.

May: Petition by Plaintiff's attorney in Cipollone to rehear earlier ruling on preemption and for a rehearing en banc (i.e. by the full court) denied by a vote of 8 to 2.

June: R.J. Reynolds Tobacco Company ends its issue advertising campaign. (Placement of all ads ended in April 1986 except for a final placement of an ad advising young people not to smoke which appeared in June.)

FTC issues a formal complaint against R.J. Reynolds Tobacco Company claiming its ad "Of Cigarettes and Science" was deceptive and misleading.

Trial of Marsee v. U.S. Tobacco Company (snuff case) in Oklahoma results in a 6-0 verdict in favor of U.S. Tobacco.

July: Administrative law judge dismisses FTC complaint against R.J. Reynolds Tobacco Company. The complaint alleged false advertising in an ad titled, "Of Cigarettes and Science." The judge ruled that the ad was an editorial protected by freedom of speech laws and not a product promotion subject to truth-in-advertising regulations.

Congressman Henry Waxman (D-CA) begins hearings on whether to ban cigarette advertising.

August: FTC appeals dismissal of a complant against R.J. Reynolds Tobacco Company and asks the five-member trade commission to overrule the dismissal and order by the administrative law judge.

Miller v. R.J. Reynolds Tobacco Company dismissed without prejudice in Ohio, but judge rules that plaintiff is liable for defendants' legal fees.

Yantiss v. R.J. Reynolds Tobacco Company dismissed with prejudice.

SECTION 4 - LITIGATION
Q'S AND A'S

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QUESTIONS AND ANSWERS

SMOKING AND HEALTH - GENERAL

1. As an attorney how do you feel about representing a major company in a industry allegedly responsible for killing hundreds of thousands of people each year?

   It makes one uncomfortable that many people believe that to be the case. We do not believe that it has been proven that cigarettes are harmful to smokers or non-smokers. It is unfortunate that what is a legitimate scientific controversy has been portrayed to the public as a closed question. It is, in fact, an open question. Millions of dollars in research are spent each year to try to resolve it.

2. How do you explain the fact that most medical experts agree that smoking does cause lung cancer?

   As a matter of fact, there are also scientists who hold the view that smoking has not been scientifically established as a cause of lung cancer. No one knows the cause or causes of lung cancer, or how it develops.

   Who are some of these scientists?

   Sir Ronald A. Fisher (deceased); Professor Philip R.J. Burch, Leeds University, England.

3. Isn't it true that every study of smoking and lung cancer has linked smoking with the disease?

   A number of studies have reported a statistical association between smoking and lung cancer but, as most scientists will agree, statistical associations do not establish cause and effect. Instead, they point up the need for clinical experiments to clarify the meaning of the association.

4. With the overwhelming mass of data presented by plaintiff's attorneys supporting his case, how can you not say that smoking isn't, at the very least, a prime suspect as a cause of lung cancer?

   Lung cancer has been statistically associated with many factors. These include where you live, your sex, personality, urbanization and several others as well as smoking. Which -- if indeed any -- of these suspects plays a role in the causation of this disease is as yet unknown.

5. If smoking doesn't cause lung cancer, how do you explain the fact that virtually all of the studies have found a statistical association between the two?

Some scientists -- such as the late famed statistician and geneticist, Sir Ronald Fisher, and more recently, Professor Phillip Burch in England -- believe the explanation might be the individual's constitutional and genetic makeup. The constitutional or genetic makeup of the individual might well result in the development of certain diseases such as lung cancer, and might also result in a predeliction for smoking.

6. Hasn't research proven that there are cancer-causing agents in tobacco smoke? Doesn't this explain the link between smoking and lung cancer?

For more than 20 years now, cancer researchers have been trying to identify components in tobacco smoke that are harmful to human health. To date, however, they have not identified any ingredient or group of ingredients, as found in tobacco smoke, that are disease producing in human beings.

7. What about a compound such as benzpyrene? As a component of tobacco smoke, hasn't research determined it's a cancer-causing agent?

Tobacco smoke is a highly complex mixture of over 4500 ingredients. We know that components act differently in isolation than when combined with other chemicals. So, even if tobacco smoke does contain a minute amount of benzpyrene, it does not mean that it will be harmful to the smoker. Remember there are thousands of other compounds in the smoke and some of these are known anti-carcinogens.

8. What about tobacco "tar?" Doesn't it produce cancer in animals?

Tobacco "tar" or tobacco smoke condensate is a product produced only in the laboratory, and is not a compound to which human smokers are exposed. Therefore, animal experiments with tobacco "tar" are not relevant. Despite great efforts by many scientists, human-type lung cancers have not been produced in laboratory animals as a result of exposure to tobacco smoke.

9. Isn't it true that a reduction in "tar" in cigarettes sold in the United States has resulted in a reduction in lung cancer among males?

The age-adjusted mortality rates from lung cancer in white males have been increasing at a decreasing rate since the middle 1960s. In the same period, the rates for females and non-white males appear to be ever-increasing.

Isn't it true that the switch to filter cigarettes by companies like R.J. Reynolds has resulted in a reduction in the number of cases of lung cancer in males?

The incidence of lung cancer among males began to level off in the United States long before reductions in "tar." Hence, scientists predicted in 1961 that the lung cancer rate for males in the United States would eventually level off, based upon data from the 1930's to 1950's, long before low "tar" or filters became popular.

10. What about the "Smoking Beagle" study? Wasn't it proven that beagles developed cancer as a result of exposure to smoke?

In 1970, Dr. Oscar Auerbach claimed that he had produced cancer in beagle dogs. His claims, however, have been repeatedly discredited in the scientific community because of certain basic methodological flaws in the experiment. Furthermore, subsequent attempts to replicate the experiment were uniformly unsuccessful. The last of these attempts by the U.S. National Cancer Institute was recently terminated because, according to one government spokesman, it was obvious that the dogs were not developing any lung lesions.

11. How can your clients refute recent reports indicating that the probability of women contracting lung cancer increases as they begin to smoke?

There has long been a wide gap between the incidence of lung cancer in males and females and this gap has not been satisfactorily explained in terms of smoking. As to the recent reports of an increase in lung cancer in women, some scientists believe that this disease has been increasing in women for many years. Furthermore, the lung cancer increase reported in women is usually of a different type from those reported as predominant in men -- adinocarcinoma -- a type not generally considered associated with smoking in the past.

Adinocarcinoma is the type of lung cancer diagnosed generally in women and non-smokers. Attitudes about adinocarcinoma's association with smoking have changed somewhat, so diagnoses of adinocarcinoma and those of squamous-cell carcinoma -- which is traditionally associated with cigarette smoking -- are combined in allegations about smoking and lung cancer.

12. What about the Doll and Hill study of several British doctors who quit smoking? Didn't it successfully pinpoint smoking as a primary cause of lung cancer?

No. Analysis of the data suggests that the incidence of lung cancer among British physicians had begun to fall prior to their cessation of smoking in the late 1950's.

13. But how does R.J. Reynolds explain the fact that numerous governmental and scientific societies have passed resolutions stating that smoking is the cause of lung cancer and other diseases in humans?

The fact that certain groups have passed such resolutions indicates how emotional the continuing controversy over smoking and health can be. Scientific issues are not settled by the passage of a resolution but by research.

14. How can the tobacco industry -- including R.J. Reynolds -- maintain that smoking is not the cause of lung cancer when all of the available evidence suggests that it is?

The fact is that all the evidence isn't one way. Studies which do not fit the smoking-causation hypothesis are not sensational, and therefore are not widely publicized. Four examples of studies which are inconsistent with a smoking-causation hypothesis:

- Several studies have shown that the age of peak incidence of lung cancer does not depend upon the age at which smoking commenced, the amount of cigarettes smoked or indeed whether or not one smokes;
- There are marked geographical differences in the incidence of lung cancer which simply cannot be explained on the basis of cigarette consumption;
- Studies of cancer in factory workers exposed to certain hazardous chemicals found that the smokers -- for some unexplained reason -- had a lower incidence of lung cancer than did the non-smokers;
- Recent studies have found a significant increase of lung cancer among non-smokers, both males and females.

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Name some of the studies referred to in the points above.

"Atlas of Cancer Mortality for U.S. Counties, 1950-1969." DHEW Publication No. (NIH) 75-780.

"Persons at High Risk of Cancer, An Approach to Cancer Etiology and Control," J.F. Fraumeni Jr., Editor. Academic Press Inc. 1975. Chapter 11, "Occupation," Philip Cole and M.B. Goldman, pp. 167-184.

15. Isn't nicotine known to cause cancer-related diseases in humans?

In 1964, after reviewing then existing literature, the Advisory Committee to the U.S. Surgeon General concluded that the small amount of nicotine absorbed by tobacco use "probably does not represent an important health hazard" to humans. Since 1964, there has been no scientific evidence which would warrant a change in this conclusion.

16. Haven't studies shown that nicotine adversely affects the cardiovascular system by increasing one's blood pressure?

Nicotine may raise blood pressure for a brief period, but no one has ever shown this to produce disease in humans. In fact, similar effects might be obtained by walking up stairs or jogging on the beach. As to long term effects, most studies show smokers to have lower blood pressure than non-smokers.

17. If "tar" and nicotine aren't relevant to human health, why has RJR emphasized "tar" and nicotine so heavily in its advertising?

The unfounded claims about the adverse health consequences of "tar" and nicotine have caused some smokers to demand lower "tar" and nicotine cigarettes. Also, many smokers prefer the lighter taste of these brands. As with any consumer product, you market cigarettes to meet consumer demands.

18. What about smoking as it relates to heart disease? Hasn't it been determined that smoking is a leading cause of heart disease?

No it isn't. Recent studies of identical twins suggest that a person's genetic background may be the most important factor. Other studies indicate that a person's personality type is the prime factor. Also, a 1979 study from Switzerland found that heart disease among women had decreased significantly during the past 25 years, while during the same period smoking among women increased.

How recent? The only one I have heard about is several years old.

One is "The Interactions of Smoking, Environment and Heredity and Their Implication for Disease Etiology," R. Cederlof, L. Friberg, T. Lundman, "Acta Medica Scandinavia," Supplement 612, September 1977.

19. How do you respond to the fact that virtually every expert agrees that smoking is a leading cause of emphysema and other respiratory problems?

Emphysema and bronchitis have been associated with many factors in addition to smoking. Which of the observed factors -- if any -- plays a role in the causation of these diseases is as yet unknown. Nor do scientists understand how these diseases develop. One of the major problems in this area is that doctors cannot agree upon diagnostic criteria for emphysema or bronchitis. Indeed, in many instances, these diseases can't even be distinguished one from the other. Furthermore, those who claim that smoking causes emphysema fail to explain why the vast majority of smokers do not develop this disease.

20. Isn't it true that smokers as a group don't live as long as non-smokers?

Some studies have reported an increased mortality among smokers compared to non-smokers, but studies involving identical twins with different smoking habits indicate that smoking has no effect whatever upon overall mortality. Studies indicate that the largest differences in life expectancy are observed between non-smokers and the lightest smokers (1 to 9 cigarettes per day). The late Professor Katz (prominent Professor of Statistics at the University of Michigan) observed that this small amount of tobacco is unlikely to account for any reported differences in life expectancy. Therefore, the reported differences between smokers and non-smokers are better explained by a genetic or constitutional hypothesis than by a smoking causation hypothesis.

21. How do you respond to claims that pregnant women who smoke risk injuring their fetus?

These claims stem from reports that babies of smoking mothers weigh less than babies of non-smoking mothers. However, it has not been scientifically established that smoking is the cause of the low birth weights. To the contrary, several major studies have concluded that the higher incidence of low birth weight babies among smokers is "due to the smoker, not the smoking."

Name the studies.

Yerushalmy, J., American Journal of Epidemiology,
93, 443, 1971.
95, 2, 1972.

Yerushalmy, J., American Journal of Obstetric Gynecology,
112, 277, 1972.
114, 571, 1972.

22. Isn't it possible for non-smokers to get lung cancer and other diseases just by being in the same room with a smoker?

There is no scientific proof that atmospheric tobacco smoke is harmful to non-smokers. Indeed, some scientists who are among the most avowed critics of smoking admit that smoking has not been established as harmful to non-smokers. For example, in June 1981 an American Cancer Society study found little, if any, increased risk of lung cancer in wives of smokers compared to wives of non-smokers. This is inconsistent with the much-publicized studies from Japan and Greece. For more information on the American Cancer Society Study, see the Journal of the National Cancer Institute, 66, 1061, 1981, by L. Garfinkel.

23. Isn't carbon monoxide in cigarettes harmful to people with cardiovascular disease?

Broadly speaking, people with cardiovascular disease are adversely affected by many things in the environment, perhaps including carbon monoxide. Carbon monoxide in the atmosphere from cigarette smoking is miniscule compared with the amount of carbon monoxide in the atmosphere from auto exhaust, factories, etc. And it has been reported that carbon monoxide from cigarette smoke doesn't have the same effects as pure carbon monoxide.

24. Haven't studies shown that carbon monoxide contributes to the development of cardiovascular disease?

No one knows what causes cardiovascular disease or how it develops. A few years ago, contrary to previous research in this field, one researcher reported that rabbits exposed to carbon monoxide had increased blood levels of cholesterol and arterial damage similar to human atherosclerosis. However, he later admitted that he has not been able to reproduce these earlier animal experiments and concluded, therefore, that carbon monoxide has not been demonstrated as being harmful to arteries.

Who is this researcher?

Astrup, P., Annual of Internal Medicine 71, 426, 1969.

S. Stender, P. Astrup, K. Kjeldsen, "Atherosclerosis," 28, 357, 1977.

(The findings of Astrup in 1969 are turned around by Astrup et. al. in 1977.)

25. Since the government has banned other "useful" products such as certain drugs, food additives and pesticides because they've been linked to cancer, why not ban cigarettes?

The Congress -- which has looked at this problem -- has decided not to ban cigarettes and for good reason: cigarettes have not been scientifically established as producing disease in humans. However, this also involves the question of freedom of choice and the role of government in a free society. For years the government and others have been making known their view that smoking is harmful to health. Today no one can credibly argue that the public is unaware of the claims against smoking, but people continue to smoke.

26. The government benefits from the excise tax generated from RJR's products. And from an economic perspective, we all know that tobacco is important to many workers in many states. But in the long-run, doesn't the cost of lost working hours and health care payments offset these benefits?

We hear much about lost work and increased cost of health care allegedly due to smoking. What people don't hear about, however, is that nearly all of the figures in this area stem from a single study which began with the unfounded premise that smoking is disease-producing in humans. The methodology, data and conclusions of this study, by the way, have been severely questioned in the scientific community.

Who did this study and where was it reported? Have there been any studies refuting it?

Professor Carl C. Seltzer, Harvard University; Professor P.R.J. Burch, Leeds University, England.

27. Isn't it true that the amount of money R.J. Reynolds spends on research is quite miniscule compared to the amount spent on advertising their products?

The two things are really not comparable. With regard to scientific research in the area of smoking and health, there is a limitation on the amount of money which can effectively be spent on good research. There is a limited number of qualified scientists to do this type of research and laboratories where it might be done. Further, no amount of money can make test animals live their lives more quickly. As to advertising, the industry spending is determined primarily by competitive market considerations.

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SECTION 5 - RJRT'S ISSUE AD CAMPAIGN

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QUESTIONS AND ANSWERS

PRODUCT LIABILITY LITIGATION - GENERAL

1. Why are so many more suits being filed against you now than in the past?

While there have been a number of suits filed recently we don't regard this as unusual. This kind of litigation which began in the early 50's has been characterized by peaks and valleys. We would characterize our recent experience as the latest peak rather than a "new wave of litigation."

2. How many suits have been tried since the first one was filed? And what has been the outcome?

As of mid-year 1986, 148 suits have been resolved. None have resulted in either a judgment or a settlement for plaintiffs. As of June 30, 1986 there were 130 suits outstanding against the tobacco industry. Of these, 83 were smoking and health suits and 43 were related to smoking and occupational exposure. Against R.J. Reynolds Tobacco Company the count was 58 smoking and health and 30 occupational exposure suits. (The remaining four cases against the industry include three self-extinguishing and one "roll-your-own.")

3. Spokesmen for R.J. Reynolds Tobacco Company have termed liability suits as unfair. How can you say they are unfair when everybody knows that cigarettes can kill you?

In the first place we don't agree with the premise of your question. Second, while there are many studies which correlate smoking with certain diseases, we would point out that these are epidemiological or statistical studies. And in spite of all the statistical associations of tobacco use with disease, no causal relationship between cigarette smoking and any disease has ever been established. Nevertheless, health claims about cigarettes are not new, they have been common knowledge for more than 400 years. Children are warned about smoking by their parents. Over the past 30 to 40 years there has been a constant drumbeat of smoking and health stories in the media.

Ultimately the decision to smoke is a matter of personal choice. If someone chooses to smoke in the face of all the health claims made against smoking, they should also be accountable for this choice. In fairness, they should not come to the bar of justice and ask to be paid because they made the wrong choice. In a similiar vein, a person who eats great quantities of red meat, ice cream, eggs and butter as a matter of choice should not, in fairness, be permitted to recover from the makers of those products for causing clogged arteries.

4. Why should cigarettes be exempt from product liability suits when other less harmful products are often held liable?

Probably the most significant difference is the warning that is on every pack of cigarettes and is a part of every cigarette advertisement. No other product has such a label. The package warning is glaring and discordant. Quite literally, the consumer must fight his way past such warnings to get to the product.

In 1965, the Congress of the United States decided how cigarettes would be treated within our society. They held extensive hearings and considered every aspect of the matter. The result was the Cigarette Labeling and Advertising Act of 1965. The Act prescribed health warnings on cigarette packages and on all advertising and relieved the states and manufacturers of any duty to go beyond the prescribed warnings. In effect, the law says that prescribed health warnings are adequate as a matter of law. This view has been tested and upheld in an April 1986 decision by the U.S. Court of Appeals for the Third Circuit.

5. Would an adverse verdict result in opening a floodgate of suits against you?

We don't think so? If we suffered an adverse verdict, at that point, the score would simply be 148 to 1. The tobacco industry, since the early 50's, has successfully resolved 148 suits and has never paid a penny in judgment or settlement. A single loss or even several losses would have to be viewed in that context.

6. Will you stop making and selling cigarettes if you should lose a suit?

Absolutely not. Cigarettes are legally manufactured, marketed, advertised and sold. Cigarettes provide pleasure and enjoyment to those who choose to smoke. We will continue to provide our customers with the finest quality products made to our exacting standards.

7. I understand the tobacco industry's view that those who have chosen to smoke since package warnings were prescribed in 1966 have been adequately warned. But how about those who started smoking before then?

Health claims about smoking are not new. King James I of England wrote "A Counterblaste to tobacco" in 1604 which closed with the words, (Smoking is)..."a custom loathsome to the eye, hateful to the nose, harmful to the brain, dangerous to the lungs, and in the black stinking fume thereof, nearest resembling the horrible Stigian smoke of the pit that is bottomless."

In fact it would be difficult to imagine a practice more warned about than smoking. It is likely that most, if not all, children are admonished repeatedly about smoking beginning at an early age and continuing until they reach adulthood. The media have carried out a constant drumbeat of communication about smoking and health issues for more than fifty years. It would be difficult to imagine another health related subject about which so much has been written or broadcast. For anyone to fairly claim they were unaware of health claims related to smoking cigarettes simply isn't credible.

8. <u>But aren't cigarettes addicting? What about the person who says he started before the warnings appeared, got hooked, and now can't quit?</u>

Cigarette smoking is not addictive. Smoking can fairly be termed a habit but its effects are not comparable to those produced by truly addicting substances such as morphine, cocaine or heroin. The Surgeon General of the United States in his 1964 Report was careful to make this distinction. According to both the Surgeon General and the World Health Organization, for a substance to be addictive it must generally produce four characteristics:

a. An overpowering compulsion to continue taking the drug and to obtain it by any means;

b. A tendency to increase the dose;

c. A psychological and physical dependence on the effects of the drug; and

d. A detrimental effect on both the individual and society.

When people attempt to broaden the definition of addiction to include cigarettes they must necessarily include other products such as coffee, chocolate, and cola drinks.

According to the Surgeon General more than 35 million Americans have quit smoking, 95 percent of whom did so without any outside help. Those who persist in the claim that smoking is addictive are probably trying to deal with the problem of freedom of choice and personal responsibility for one's own behavior, which marks product liability cases, by trying to provide an excuse.

9. What will be the basis for your defense in these suits? In the past you have relied on the cigarette pack health warnings. Will you continue to rely on these warnings?

The central issue in all these cases is freedom of choice and accountability for one's own decisions. Fairly, should a person who has chosen to smoke in the face of all the health claims made about cigarettes be able to come to the bar of justice 20 or 30 years later and say "I made the wrong decision, I've suffered an injury, now pay me." We think not. And whenever this question has been considered by juries they agree with our view.

As to whether people have been adequately warned regarding the health claims against smoking, the decision of the U.S. Court of Appeals for the Third Circuit is quite clear on this question. The court noted that the language in the Federal Cigarette Labeling and Advertising statute of 1965 clearly specified that states could not add health warning requirements beyond those required by the federal law. The Court said that the warnings are adequate as a matter of law. And significantly, the law also protects the right of cigarette manufacturers to freely market, promote and advertise their products.

10. Some of your critics have suggested that your advertising has the effect of negating the prescribed health warnings?

Well, when you think about it your common sense tells you this kind of charge simply isn't credible. The idea that the portrayal of adults in a pleasant setting playing volleyball or going horseback riding through the surf can overcome the glaring and discordant health warning on every cigarette pack and ad simply isn't credible.

11. How about the charge that cigarette advertising is designed to get young people to smoke?

The premise of this question, that advertising has the power to persuade a non-smoking person to begin smoking is simply not borne out by the facts. Research has consistently demonstrated that people of any age who choose to smoke do so because of peer influence. Advertising is effective only in getting people who already smoke to try your brand. R.J. Reynolds Tobacco Company believes that smoking is an adult pursuit. The decision of whether to smoke should be made by adults after mature consideration of the facts.

12. Product liability litigation must be costing your company a lot of money. How much did R.J. Reynolds Tobacco Company spend on litigation in 1985?

That figure is proprietary. We never discuss amounts spent on legal fees or, for that matter, any other kind of services purchased by the company.

13. How many outside law firms are representing the company and who are they?

That information is proprietary. We simply do not discuss it.

14. Your critics have accused your company of a "head in the sand" attitude regarding the 25,000 or so epidemiological studies that show that smoking "causes" cancer, emphysema and heart disease. How can you, in good conscience, ignore such an overwhelming mass of evidence.

The short answer is that regardless of the mass of statistical data which associates smoking with various diseases, science has, as yet, been unable to demonstrate a causal relationship between smoking and any disease.

Even our worst critics would have to acknowledge that smoking is but one of many risk factors that have been associated with diseases. Further, no one has been able to establish a one-to-one relationship between smoking and any disease. The fact of the matter is that at the basic cellular level, no one knows what causes cancer or heart disease or obstructive lung diseases. No one knows why one cell becomes cancerous and another doesn't. And no one knows why one person with the exact same exposure to a suspected agent may get a disease and the person next to him, with the same exposure may not.

All of the diseases associated statistically with smoking are multi-factorial. In heart disease, for example, statistically-based studies of the disease associate it with a number of risk factors such as genetic make-up, cholesterol, lack of exercise, stress and others as well as smoking. To say that any one factor has "caused" the disease in a particular individual just doesn't make good - sense. The tobacco industry isn't trying to be hard-headed or to ignore evidence, but we believe quite strongly that there is a fundamental distinction that must be made between cause and risk factor.

15. What proof will it take to convince your company of a causal link between smoking and lung cancer?

We subscribe to the proof criteria that was set forth in the 1964 Surgeon General's Report. In that report the categoric statement was made that "Statistical methods cannot establish proof of a causal relationship in an association" (emphasis added).... the mere establishment of a statistical association between the use of tobacco and a disease is not enough..." to establish cause. The Surgeon General's report also notes that "... attempts to produce bronchogenic carcinoma (lung cancer) directly with tobacco extracts, smoke or condensates applied to the lung or the tracheobronchial tree of experimental animals have not been successful."

Between 1964 and 1982 literally tens of millions of dollars were spent on experimental studies with animals in which whole smoke was introduced into the animals' lungs in an attempt to induce bronchogenic carcinoma. According to the 1982 Surgeon General's report the results of these "major efforts were negative...not a single case of lung cancer was induced". Perhaps because of inability to produce experimental evidence, the '82 report went on to say that epidemiological association was now sufficient to establish causation. In effect, since the evidence needed to prove a causal relationship could not be produced, the criteria for proof was changed.

16. Are the tobacco companies acting jointly in the defense of product liability suits?

There are a number of cases where several tobacco companies have been named as defendants. In such cases we are coordinating our defenses with our co-defendants.

17. If you truly believe that smoking does not cause lung cancer and heart disease, how could you acquiesce and accept a requirement to place warning labels on cigarette packs which specifically say that smoking causes lung cancer and other diseases?

When hearings were held by the Congress on smoking and health, the industry testified in opposition to the warnings. Congress, however, after hearing the testimony of many factions including health authorities, economists, farmers, retailers and scientists, decided the way in which this issue would be treated within our society. In 1965, Congress passed the Federal Cigarette Labeling and Advertising Act which required warnings on cigarette packs and in advertising. The law clearly prescribed that with required warnings, cigarettes could be legally manufacturerd, marketed, promoted, advertised and sold in interstate commerce. Since enactment, the cigarette industry has scrupulously sought to comply with the law.

18. Nicotine in cigarettes is acknowledged to be a powerful drug. Do the pschyo-active properties of nicotine in fact make cigarettes addictive?

It is true that nicotine is pschyo-active. But so too are products like coffee, tea and chocolate. All produce changes in brain-wave patterns, increased blood pressure and hormone release. This does not mean that any of these products are addictive like cocaine, heroin or morphine.

19. In view of the overwhelming weight of epidemological evidence linking smoking cigarettes with lung cancer, how can you continue to insist that smoking doesn't cause lung cancer?

Well to start with, we are not unmindful of the epidemological data. And in fairness, we acknowledge the data which correlates smoking with lung cancer. But also in fairness, you must understand there are also many other factors which correlate with lung cancer. For instance, there are such factors as air pollution, exposure to radiation, exposure to industrial fumes and probably quite important is the genetic susceptibility to lung cancer that people inherit from their parents.

Another major factor that should be kept in mind is that lung cancer is essentially a disease of old age. The average age of onset is about 65. And this is true whether one is a heavy smoker, a light smoker or has never smoked at all. It's true whether one has smoked for 10 years or 10 minutes. Whether one smoked four packs a day or not at all. In fact, 95 percent of even heavy smokers never contract lung cancer.

Advertising

1. Isn't it true that cigarette ads portray smoking as a sophisticated and glamorous activity to entice people to smoke?

No. Our advertising is designed to take business away from the competition, to get those who already smoke to try our brand. All the studies that have been done on cigarette advertising support this view.

People don't start smoking because of exposure to ads. The decision to smoke is influenced primarily by the example of parents, friends, teachers and the social pressures of peer groups.

(Dr. Scott Wand of the Wharton School is an authority on this subject.)

2. If advertising is ineffective in getting people to start smoking, won't you eventually go out of the cigarette business?

We don't think so. People smoke for many reasons but studies show that advertising has little if anything to do with why people choose to smoke. People have chosen to smoke long before the advent of sophisticated advertising techniques. Most likely people smoke because it gives them pleasure. The decision to smoke has been attributed in most studies to the example of parents, friends and the social influence of peers.

3. Don't your ads, by implication, portray smoking as a healthful activity?

No. Our ads do depict smokers enjoying active, modern lifestyles. But our ads do not suggest that healthy active lifestyles are the result of smoking. In fact, every package and every ad contains a glaring and discordant health warning by the Surgeon General concerning the health risks that have been associated with smoking.

4. Would a cigarette advertising ban reduce cigarette consumption?

Not in our view. The experience within other countries where cigarette advertising has been banned for many years demonstrates that more often than not the opposite is true. In places where cigarette advertising has been banned, consumption does not decrease and in some countries has even increased. If one's objective is to reduce cigarette consumption, clearly banning advertising is not the way to accomplish it.

5. If an ad ban would not reduce consumption, why are the cigarette companies against it? Wouldn't they make more money by not spending on advertising and promotion?

The objective of cigarette advertising is to take smokers away from the competition. Advertising expenditures are well spent in achieving this goal.

6. How do you answer the charge that newspapers and magazines are reluctant to carry anti-smoking articles out of fear that cigarette companies will withdraw their advertising?

The sheer volume of anti-smoking articles which appear in the same publications which carry cigarette ads gives the lie to this charge.

QUESTIONS AND ANSWERS

REGARDING R.J. REYNOLDS TOBACCO COMPANY'S

1985 ISSUES AD CAMPAIGN

I. GENERAL QUESTIONS

1. Issue ads seem to suggest an attempt by R.J. Reynolds to reduce the impact of health warnings. If this is the case, will R.J. Reynolds admit that could be the effect of the ads -- at least to some smokers?

It was not our intent to reduce the impact of the health warnings. Our intent was to discuss R.J. Reynolds' point of view that whether smoking causes the diseases with which it is associated statistically is still an open question and not a closed issue. Our intent also is to discuss our positions on a number of other issues such as fire safety and our firm belief that young people should not smoke. We believe the public is entitled to know our views on issues.

It has been shown in various studies that well over 90 percent of the public believes smoking is harmful to health, and we do not believe that figure will be changed by anything we say.

2. Some plintiff's lawyers allege that actions by tobacco companies such as R.J. Reynolds mitigate the impact of health warnings. As an attorney for R.J. Reynolds, don't you think so-called issue ads will strengthen the plaintiff's case in these suits since the bottom line is they do create doubt about smoking as the cause of diseases?

It was not our intent to reduce the impact of the health warnings. Our intent was to discuss R.J. Reynolds' point of view that whether smoking causes the diseases with which it is associated statistically is still an open question and not a closed issue. Our intent also was to discuss our positions on a number of other issues such as fire safety and our firm belief that young people should not smoke.

It has been shown in various studies that well over 90 percent of the public believes smoking is harmful to health, and we do not believe that figure will be changed by anything we say.

3. Why did R.J. Reynolds introduce later in its campaign what appeared to be stronger ads compared to those run earlier, they appear to be much more controversial?

When we first introduced our program, we said we would be presenting our point of view on a variety of issues. This was simply a continuation of that program.

II. REFERRING SPECIFICALLY TO RJR'S AD "OF CIGARETTES AND SCIENCE":

1. If what the company said in its ad is true, why are so many scientists still saying there's no doubt that smoking is a major cause of lung cancer, emphysema and other diseases? What studies? Who are the scientists?

We were discussing heart disease in that ad.

We recognize that many doctors and scientists believe that smoking causes heart disease, and we respect their right to hold that view.

We recognize that there is a body of evidence, based largely on statistical association, which has led some people, including many doctors and scientists, to claim that smoking causes heart disease. There are, however, other studies which fail to support the claim and other doctors and scientists who do not believe it has been scientifically proved that smoking causes heart disease.

The reason for the controversy is that statistical correlation cannot be used to prove a cause and effect relationship. (In fact, even the Surgeon General's reports have made that observation when they said:

> "Statistical methods cannot establish proof of a causal relationship in an association. The causal significance of an association is a matter of judgment which goes beyond any statement of statistical probability.")

It was because of this basic scientific principle that the Multiple Risk Factor Intervention Trial Study, the MRFIT Study, was conducted. It was done to prove that the risk factors, those factors statistically associated with coronary heart disease, actually caused the disease. As we pointed out in the ad, the MRFIT Study failed to support the hypothesis that the risk factors studied in MRFIT, especially cigarette smoking, are causes of coronary heart disease deaths.

Nor is the MRFIT Study an isolated case. Other similar studies have found that reducing smoking had no significant effect on rates of cardiovascular disease.

We don't claim that these studies prove that smoking does not cause heart disease. We do say that these studies strongly suggest that the idea of the importance of these currently identified "risk factors" affecting coronary heart disease mortality should be seriously reexamined by the scientific community.

2. Are you suggesting the scientists making these statements are dishonest?

Not at all. They make these claims based on the belief that the statistical associations provide sufficient support, from a public health point of view, to come to such conclusions.

You can see that in the wording of the 1979 Surgeon General report which said:

> "Smoking is causally related to coronary heart disease in the common sense of that idea and for the purposes of preventive medicine."

3. Doesn't this ad suggest there's some sort of "scientific conspiracy" to mislead the public about smoking and diseases?

Of course not. These people sincerely believe what they're saying, and we respect their rights to hold that view. But we do believe there may be some excessive enthusiasm for the belief that controlling of "risk factors" is able to affect coronary heart disease mortality.

In fact, we believe the MRFIT Study, and others, provide sufficient reason for science to begin to reexamine the concept that these currently identified "risk factors" can affect coronary heart disease death.

4. Aren't there many studies that have proven smoking is a major factor contributing to heart disease?

There have been, and continue to be, studies which show statistical association between heart disease and smoking and other factors. The most frequently referenced of these is the well-known Framingham Study, which was important in the development of the current "risk factors."

But there have also been other intervention studies similar to the MRFIT Study which have not shown that reducing smoking can significantly affect mortality from cardiovascular disease. (One of these was a study in Oslo, Norway reported in 1981 and 1982, and another was reported by Rose and Hamilton in 1978.)

5. Are there any doctors who are questioning the link between smoking and heart disease?

Dr. Carl Seltzer of Harvard University and Dr. Edwin Fisher of the University of Pittsburgh, for example.

6. Are there any doctors we can call who will support R.J. Reynolds' position on this issue?

I think that either Dr. Carl Seltzer of Harvard University or Dr. Edwin Fisher of the University of Pittsburgh would express their viewpoint that there is no scientific proof that smoking causes heart disease.

7. Are there any scientists who have questioned the findings of MRFIT?

There are some people who have claimed that the MRFIT Study was wrong. We are not in a position to argue that point. All we can say is that the results speak for themselves.

There has also been a lot of scientific comment about the results of the MRFIT Study, namely, that it did not prove that reducing smoking, cholesterol levels, and blood pressure levels was able to result in a reduction of deaths from coronary heart disease.

G.D. Lundberg said in the Journal of the American Medical Association that "unfortunately the fundamental question facing the investigators at the beginning of the experiment remained unanswered." R.A. Stallones said in the American Journal of Epidemiology that "my conclusion is that the best explanation for the failure to detect a beneficial effect in MRFIT is that no benefits accrued." G. Kolata said in Science magazine that "so, on the face if it, it looks like risk factor reduction may not be beneficial, contrary to the current medical dogma." The Lancet, a British medical journal, said "the results prove nothing, and we must turn elsewhere to answer the question, Does prevention work?"

8. Aside from MRFIT, does R.J. Reynolds have any other evidence to support its claim that smoking does not contribute to heart disease?

Please understand that it is extremely difficult to prove a negative. There are studies which fail to demonstrate the statistical association between smoking and heart disease that has been seen in other studies. In addition, there has been no experimental study ever conducted which has shown this relationship to exist.

Also, please recognize that the MRFIT Study is not just another study. The MRFIT Study was a major undertaking, probably the biggest intervention study, maybe the biggest experimental research study on heart disease, ever conducted in this country. It lasted ten years, involved over 12,000 men, and cost about $115,000,000. This was a massive and very important study, and the fact that its results failed to demonstrate that reducing those three risk factors would result in reduced coronary heart disease is a very important finding.

9. What, if any, scientific work is the tobacco industry, including R.J. Reynolds, funding that relates to smoking and heart disease?

R.J. Reynolds does not do smoking and health research in its own laboratories. We decided years ago that any research that we might do on the subject of smoking and health, particularly any research which failed to support the claim that smoking caused disease, would receive virtually no credibility in the media and among some of the scientific community. That's the reason that our funding of such research has been channeled to the Council for Tobacco Research.

From the time it was organized the CTR has remained completely autonomous in its programs of grants and aid and contracts for research with institutions and laboratories. It operates no research facility but works with the guidance of twelve independent scientists in reviewing research applications and selecting those research projects it funds. Additionally, each grantee funded by the Council for Tobacco Research has complete freedom to publish research results, whatever they may be.

III. "SMOKING AND HEALTH: SOME FACTS YOU'VE NEVER HEARD ABOUT"

1. If what R.J. Reynolds says is true, why are so many scientists saying there is no doubt that smoking is a major cause of lung cancer?

We recognize that many doctors and scientists believe that smoking causes lung cancer, and we respect their right to hold that view.

We recognize that there is a body of evidence, much of it based on statistical association, which has led some people, including many doctors and scientists, to claim that smoking causes lung cancer. There is another body of evidence which fails to support the claim, and there are also doctors and scientists who believe it has not been scientifically proved that smoking causes lung cancer.

The controversy exists because no one really knows what causes a cell to change from a normal state to a state of uncontrolled growth and malignancy. No one knows what causes cancer or the mechanisms whereby it develops. Until that is known, we cannot know whether smoking is a cause or not.

2. How much money does R.J. Reynolds Tobacco contribute each year to scientific research on smoking and health issues?

Since the industry first started funding smoking and health research, well over $120,000,000 has been committed, and R.J. Reynolds has contributed about one-third of that money. While year-to-year figures may vary, it was most recently compiled in 1982. That year, the industry contributed $7,000,000, of which about one-third was contributed by R.J. Reynolds.

3. How is the funding provided?

Most of the funding is provided through the Council for Tobacco Research.

The Council for Tobacco Research was established by the industry to provide financial support for research by independent scientists into tobacco use and health. The Council for Tobacco Research is completely autonomous in its programs. It operates no research facility but works with the guidance of twelve independent scientists in reviewing research applications and selecting those research projects it funds.

4. Don't inhalation studies generally support the evidence from statistical studies?

There have been a number of smoke inhalation studies which have been reported which have consistently not done what they set out to do -- that is, to produce the kind of lung cancer observed among humans.

5. Why are you so sure the NCI would have published its dog study results if they were positive?

Of course, our certainty is an assumption. But had it succeeded in its objectives, it would have been the first inhalation study that actually induced human type lung cancer in animals. I don't believe anybody could seriously question whether they would have published results like that.

6. In your ads you said when the answers are found you'll let the public know. Does that also mean that R.J. Reynolds will send out news releases and advertisements if someone proves a definite causal relationship between smoking and diseases?

I can't make any commitments as to how we might communicate it, but I can assure you that we will not terminate any studies or suppress any results.

7. Tell us what, if any, action R.J. Reynolds will take regarding its products if something like this happens? Will your client stop selling cigarettes?

If anyone ever demonstrates that there is any element or component in cigarette smoke that causes a specific disease, we will do everything possible to remove that element or component.

If something like that is ever discovered, it will almost necessarily be something quite specific, and we feel our research and development capabilities will be able to deal with it.

IV. "WE'RE NOT RAISING QUESTIONS - WE'RE SEEKING ANSWERS"

1. Is this ad an example of the type of dishonesty you've implied exists among the scientists who are against tobacco companies such as R.J. Reynolds? After all, it's obvious from your client's three most recent ads that they're trying to keep smokers smoking by making them feel more comfortable about what they're doing. As the attorney for R.J. Reynolds, what is your response to this belief?

First of all, we have not implied that there is any dishonesty existing among scientists to hold a point of view which is different from ours. We recognize that many doctors and scientists believe that smoking causes disease, and we respect their right to hold that view.

But I hope you will understand that this was in no way an effort to suggest to people that it is okay to smoke or to make people more comfortable with their smoking. Our entire program, including this particular ad, was an effort to discuss R.J. Reynolds' point of view on a variety of smoking issues, from the need for courtesy between smokers and non-smokers and our belief that young people should not smoke to discussions of the point that the smoking and health issue is, in our opinion, an open controversy and not a closed case.

Our objective was fairly straightforward. We noticed a trend toward more and more emotionalism, fueled by rumor and rhetoric, in public discussions of smoking issues. We want discussions of smoking issues to occur in a rational, logical environment among reasonable people who recognize that there is more than one side to the issue.

2. Tell us how much money for smoking and health research has been raised by private health groups since 1954. As the attorney for R.J. Reynolds, it would stand to reason that you would know since you claim your client has provided more.

We don't know precisely how much money the private health groups have spent since 1954. That data is very hard to accumulate because it is not always made available. But from what evidence the Tobacco Institute has, we believe that the industry's $120,000,000 greatly exceeds the private funding. In 1982 for example, the American Cancer Society and the American Heart Association devoted about $1,000,000 to tobacco health research, while the tobacco industry contributed more than $7,000,000.

In fact, we hope the private health agencies will report the amount of funding they have committed to smoking and health research. The information would be quite interesting.

3. Who are the eminent, independent scientists who determine who gets grants for CTR?

Dr. Leon Jacobson	Dr. Peter Hawley
Dr. Sheldon Sommers	Dr. Barry Pierce
Dr. Richard Bing	Dr. Gorden Sato
Dr. Roswell Bontwell	Dr. Drummond Bowden
Dr. Michael James Brennan	Dr. William Gardner
Dr. Joseph Feldman	Dr. Henry Lynch

4. Who at CTR can we talk to to find out more about their work?

The Scientific Director is Dr. Sheldon C. Sommers, and he can be contacted for information about CTR.

5. In some of its other ads, Reynolds claims that studies supporting its argument never were published. Has the CTR or Reynolds ever stopped publication of a study or cancelled funding for a study that ran the risk of producing unfavorable results?

The only reference to any study that has not been published was the beagle dog study mentioned in one of our other ads. We have suggested that when studies that fail to support the claim that smoking causes disease are published in medical journals and other peer review publications, they very rarely are reported in the public news media.

That's not terribly surprising, because a study whose author said they were unable to conclude that some relationship existed between smoking and whatever they were studying is simply not a very interesting news story. The real drama is in the studies which do claim these relationships.

The Council for Tobacco Research has never cancelled funding for a study based on the results the study was producing. Also, the CTR has no control over the publication of these studies. The scientists conducting the research are free to publish as they see fit.

6. You mentioned earlier that CTR received $120,000,000 for research. Exactly how much of this $120,000,000 was funded by Reynolds?

R.J. Reynolds is about one-third of the industry, and we have provided about one-third of the funding that has been given to CTR over the years.

7. How much, if any, health-related research does Reynolds do in its own laboratories?

R.J. Reynolds does not do smoking and health research in its own laboratories. We decided years ago that any research that we might do on the subject of smoking and health, particularly any research which failed to support the claim that smoking caused disease, would receive virtually no credibility in the media and among some of the scientific community. That's the reason that our funding of such research has been channeled to the Council for Tobacco Research.

That organization remains completely autonomous in its programs of grants and aid and contracts for research with institutions and laboratories. It operates no research facility but works with the guidance of twelve independent scientists in reviewing research applications and selecting those research projects it funds. Additionally, each grantee funded by the Council for Tobacco Research has complete freedom to publish research results, whatever they may be.

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ISSUE AD COPY

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Can we have an open debate about smoking?

The issues that surround smoking are so complex, and so emotional, it's hard to debate them objectively.

In fact, many of you probably believe there is nothing to debate.

Over the years, you've heard so many negative reports about smoking and health—and so little to challenge these reports—that you may assume the case against smoking is closed.

But this is far from the truth.

Studies which conclude that smoking causes disease have regularly ignored significant evidence to the contrary. These scientific findings come from research completely independent of the tobacco industry.

We at R.J. Reynolds think you will find such evidence very interesting. Because we think reasonable people who analyze it may come to see this issue not as a closed case, but as an open controversy.

We know some of you may be suspicious of what we'll say, simply because we're a cigarette company.

We know some of you may question our motives.

But we also know that by keeping silent, we've contributed to this climate of doubt and distrust. We may also have created the mistaken impression that we have nothing to say on these issues.

That is why we've decided to speak out now, and why we intend to continue speaking out in the future.

During the coming months we will discuss a number of key questions relating to smoking and health. We will also explore other important issues including relations between smokers and non-smokers, smoking among our youth, and "passive smoking."

Some of the things we say may surprise you. Even the fact that we say them may prove controversial.

But we won't shy away from the controversy because, quite frankly, that's our whole point.

We don't say there are no questions about smoking. Just the opposite. We say there are lots of questions—but, as yet, no simple answers.

Like any controversy, this one has more than one side. We hope the debate will be an open one.

R.J. Reynolds Tobacco Company

What not to do in bed.

You can read.
You can rest.
You can sleep.
You can make phone calls.
You can eat breakfast.
You can watch television.
You can listen to music.
You can exercise.
You can snore.
You can even eat crackers—
provided you're alone.
And yes, you can snuggle.
But don't ever light up a cigarette
when you're in bed.
Because if you doze off just once,
all your dreams can go up in smoke.

R.J. Reynolds Tobacco Company

A message from those who don't to those who do.

We're uncomfortable.

To us, the smoke from your cigarettes can be anything from a minor nuisance to a real annoyance.

We're frustrated.

Even though we've chosen not to smoke, we're exposed to second-hand smoke anyway.

We feel a little powerless.

Because you can invade our privacy without even trying. Often without noticing.

And sometimes when we speak up and let you know how we feel, you react as though *we* were the bad guys.

We're not fanatics. We're not out to deprive you of something you enjoy. We don't want to be your enemies.

We just wish you'd be more considerate and responsible about how, when, and where you smoke.

We know you've got rights and feelings. We just want you to respect our rights and feelings, as well.

A message from those who do to those who don't.

We're on the spot.

Smoking is something we consider to be a very personal choice, yet it's become a very public issue.

We're confused.

Smoking is something that gives us enjoyment, but it gives you offense.

We feel singled out.

We're doing something perfectly legal, yet we're often segregated, discriminated against, even legislated against.

Total strangers feel free to abuse us verbally in public without warning.

We're not criminals. We don't mean to bother or offend you. And we don't like confrontations with you.

We're just doing something we enjoy, and trying to understand your concerns.

We know you've got rights and feelings. We just want you to respect our rights and feelings, as well.

Brought to you in the interest of common courtesy by

R.J. Reynolds Tobacco Company

Smoking in public: Let's separate fact from friction.

There has always been some friction between smokers and non-smokers. But lately this friction has grown more heated.

The controversy has been fueled by questionable reports which claim that "second-hand smoke" is a cause of serious diseases among non-smokers.

But, in fact, there is little evidence—and certainly nothing which proves scientifically—that cigarette smoke causes disease in non-smokers.

Skeptics might call this the wishful thinking of a tobacco company. But consider the scientific judgment of some of the leading authorities in the field—including outspoken critics of smoking.

For example, in 1983 the organizer of an international conference on environmental tobacco smoke (ETS) summarized the evidence on lung cancer as follows: "An overall evaluation based upon available scientific data leads to the conclusion that an increased risk for non-smokers from ETS exposure has not been established."

Even the chief statistician of the American Cancer Society, Lawrence Garfinkel, has gone on record as saying, "passive smoking may be a political matter, but it is not a main issue in terms of health policy."

Which brings us back to our original point: cigarette smoke can be very annoying to non-smokers.

But how shall we as a society deal with this problem?

Confrontation? Segregation? Legislation?

No. We think annoyance is neither a governmental problem nor a medical problem. It's a people problem.

Smokers and non-smokers have to talk to one another. Not yell, preach, threaten, badger or bully. Talk.

Smokers can help by being more considerate and responsible. Non-smokers can help by being more tolerant. And both groups can help by showing more respect for each other's rights and feelings.

But eliminating rumor and rhetoric will help most of all.

Because when you stick to the facts, it's a lot easier to deal with the friction.

R.J. Reynolds Tobacco Company

Some surprising advice to young people from R J Reynolds Tobacco.

Don't smoke.

For one thing, smoking has always been an adult custom. And even for adults, smoking has become very controversial.

So even though we're a tobacco company, we don't think it's a good idea for young people to smoke.

Now, we know that giving this kind of advice to young people can sometimes backfire.

But if you take up smoking just to prove you're an adult, you're really proving just the opposite.

Because deciding to smoke or not to smoke is something you should do when you don't have anything to prove.

Think it over.

After all, you may not be old enough to smoke. But you're old enough to think.

R.J. Reynolds Tobacco Company

We don't advertise to children.

Who are you kidding?

The newspapers and magazines and billboards are filled with cigarette ads. Kids can't help but see them.

How can you expect us to believe you're not trying to reach and influence our children?

We're not surprised if many people feel this way—especially when years of negative publicity have made them totally cynical about our industry.

Nevertheless, we'd like to set the record straight.

First of all, we don't want young people to smoke. And we're running ads aimed specifically at young people advising them that we think smoking is strictly for adults.

Second, research shows that among all the factors that can influence a young person to start smoking, advertising is insignificant. Kids just don't pay attention to cigarette ads, and that's exactly as it should be.

Finally—and this is sometimes hard for people outside the marketing field to understand—all of our cigarette ads are what we call "brand advertising." Its purpose is to get smokers of competitive products to switch to one of our brands, and to build the loyalty of those who already smoke one of our brands.

At the present there are some 200 different cigarette brands for sale in the U.S. Many of them have only a very small fraction of the total cigarette market. Getting smokers to switch is virtually the only way a cigarette brand can meaningfully increase its business.

That's why we don't advertise to young people.

Of course, if you'd like to share *this* ad with your children, that would be just fine with us.

R.J. Reynolds Tobacco Company

Second-hand smoke: Let's clear the air.

Can cigarette smoke in the air cause disease in non-smokers?

That's an emotional question for smokers and non-smokers alike. So we'll try to set the record straight in the most direct way we know.

There is little evidence—and certainly nothing which proves scientifically—that cigarette smoke causes disease among non-smokers.

You don't have to take our word for it.

U.S. Surgeon General Julius B. Richmond—who was no friend of smoking—said in his 1979 Report: "Healthy non-smokers exposed to cigarette smoke have little or no physiologic response to the smoke, and what response does occur may be due to psychological factors."

And in the 1982 Report, Surgeon General C. Everett Koop could not conclude that passive smoking is a cause of cancer in non-smokers.

The director of the National Heart, Lung and Blood Institute, Dr. Claude Lenfant, has been one of the tobacco industry's sharpest critics. Yet Dr. Lenfant stated in 1980 (and we believe it remains true today) that "the evidence that passive smoking in a general environment has health effects remains sparse, incomplete and sometimes unconvincing."

We've decided to speak out on passive smoking because there is so much rumor and rhetoric on this subject today. And we intend to continue, from time to time, to speak out on other topics of concern to you and to us.

Our critics may try to discredit these messages as self-serving. In a sense, they will be right. We will challenge allegations that are unproven and attacks we think are unfounded. If that is self-serving, so be it.

The questions that surround smoking raise many important issues. We believe that you're entitled to hear all sides of these controversies.

R.J. Reynolds Tobacco Company

Second-Hand Smoke: The Myth and The Reality.

Many non-smokers are annoyed by cigarette smoke. This is a reality that's been with us for a long time.

Lately, however, many non-smokers have come to believe that cigarette smoke in the air can actually cause disease.

But, in fact, there is little evidence—and certainly nothing which proves scientifically—that cigarette smoke causes disease in non-smokers.

We know this statement may seem biased. But it is supported by findings and views of independent scientists—including some of the tobacco industry's biggest critics.

Lawrence Garfinkel of the American Cancer Society, for example. Mr. Garfinkel, who is the Society's chief statistician, published a study in 1981 covering over 175,000 people, and reported that "passive smoking" had "very little, if any" effect on lung cancer rates among non-smokers.

You may have seen reports stating that in the course of an evening, a non-smoker could breathe in an amount of smoke equivalent to several cigarettes or more.

But a scientific study by the Harvard School of Public Health, conducted in various public places, found that non-smokers might inhale anywhere *from 1/1000th to 1/100th of one filter cigarette per hour.* At that rate, it would take you at least 4 days to inhale the equivalent of a single cigarette.

Often our own concerns about our health can take an unproven claim and magnify it out of all proportion; so, what begins as a misconception turns into a frightening myth.

Is "second-hand smoke" one of these myths? We hope the information we've offered will help you sort out some of the realities.

R.J. Reynolds Tobacco Company

How to handle peer pressure.

If some of your friends smoke, and they make you feel like you should smoke, too, that's "peer pressure."

But even though we're a cigarette company, we think young people shouldn't smoke. Even the decision to smoke or not to smoke should wait until you're an adult.

So we put together these ideas to help you recognize peer pressure—and resist it.

Tactic #1:	*Go ahead and take a puff—what's the matter, are you chicken?*
Answer:	You must think I'm pretty dumb to fall for that one. It takes a lot more guts to do your own thing than to just go along with the crowd.
Tactic #2:	*Come on, all the cool kids smoke.*
Answer:	Maybe the kids who smoke are trying to *look* cool. But if they really *were* cool, maybe they wouldn't have to try so hard.
Tactic #3:	*Hey, I'm your friend—would I steer you wrong?*
Answer:	Friends are people who like you for who you are, not for what they want you to be. If you're really my friend, back off.
Tactic #4:	*Do you want everybody to think you're a nerd?*
Answer:	Sure I care what other kids think of me. But if they base their opinions on stuff like smoking, their opinions aren't worth much.
Tactic #5:	*I bet you're just scared your parents will find out.*
Answer:	I wouldn't blame my parents for getting teed off. How can I expect them to treat me like an adult if I sneak around and act like a kid?

It's natural for you to want to be just like your friends.

But if you don't smoke, maybe your friends will want to be just like you.

R.J. Reynolds Tobacco Company

Passive smoking: An active controversy.

Periodically the public hears about an individual scientific study which claims to show that "environmental tobacco smoke" (ETS) may be harmful to non-smokers. These reports usually receive sensational media coverage.

Yet, three times within two years, groups of distinguished experts have gathered to review not just one study but the whole body of evidence on this subject. In all three cases, the scientists came to similar—and far less sensational—conclusions.

Yet the media have remained almost silent.

In March 1983 there was the "Second Workshop on Environmental Tobacco Smoke" in Geneva, Switzerland. In May 1983 there was the "Workshop on Respiratory Effects of Involuntary Smoke Exposure" in Bethesda, Maryland.

And, most recently, in April 1984, leading experts from around the world gathered in Vienna for a symposium, "Passive Smoking from a Medical Point of View."

After this symposium was over, the presidents of the two organizing groups issued a press release summarizing their findings.

The summary said, "the connection between [ETS] and lung cancer has not been scientifically established to date." It also said "there is a high probability that cardiovascular damage due to [ETS] can be ruled out in healthy people."

And it went on to say, "Should lawmakers wish to take legislative measures with regard to [ETS], they will, for the present, not be able to base their efforts on a demonstrated health hazard from [ETS]."

Perhaps the media would say they cannot be blamed for devoting little attention to what some would consider "non-news." But we at R.J. Reynolds are concerned about the effects such one-sided coverage may be having on the public.

For today, many non-smokers who once saw cigarette smoke merely as an annoyance now view it as a threat to their health. Their growing alarm is being translated into heightened social strife and unfair anti-smoker legislation.

We believe these actions are unwarranted by the scientific facts—and that it is rhetoric, more than research, which makes passive smoking an active controversy.

R.J. Reynolds Tobacco Company

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Does smoking really make you look more grown up?

It's a crazy world.

Most adults we know would love to look younger than they really are. While most young people are busy trying to look more adult.

This is one reason why many young people take up smoking.

Well, we wish they wouldn't.

For one thing, it doesn't work. A fifteen-year-old smoking a cigarette looks like nothing more or less than a fifteen-year-old smoking a cigarette.

Even though we're a tobacco company, we don't think young people should smoke. There is plenty of time later on to think about whether or not smoking is right for you.

Besides, when you think about it, being grown up is highly overrated. You have to go to work, pay taxes, wear normal clothes and raise kids who grow up to be teenagers.

Why be in such a hurry?

R.J. Reynolds Tobacco Company

Some straight talk about smoking for young people.

We're R.J. Reynolds Tobacco, and we're urging you not to smoke.

We're saying this because, throughout the world, smoking has always been an adult custom. And because today, even among adults, smoking is controversial.

Your first reaction might be to ignore this advice. Maybe you feel we're talking to you as if you were a child. And you probably don't think of yourself that way.

But just because you're no longer a child doesn't mean you're already an adult. And if you take up smoking just to prove you're not a kid, you're kidding yourself.

So please don't smoke. You'll have plenty of time as an adult to decide whether smoking is right for you.

That's about as straight as we can put it.

R.J. Reynolds Tobacco Company

The most inflammatory question of our time.

"Hey, would you put out that cigarette?"

Just seven little words. But in today's over-heated climate of opinion, they can make sparks fly.

For with all the rhetoric about "second-hand smoke," many non-smokers are beginning to feel not just bothered but threatened by cigarettes.

And with all the talk about anti-smoking legislation, many smokers are beginning to feel threatened by non-smokers.

This is not exactly a recipe for social harmony. In fact, it's practically a guarantee of further discord.

Since we have discussed scientific aspects of the "passive smoking" controversy in previous messages, we'd like to focus here on the social questions.

Will more confrontation or more segregation produce less abrasion? Do we solve anything by creating yet another way to divide our society? Shouldn't all of us be wary of inviting government to involve itself further in our private lives?

At R.J. Reynolds, we see an alternative.

We think we should start not by raising barriers, but by lowering our voices. We think smokers and non-smokers can work out their differences together, in a spirit of tolerance and fairness and respect for each other's rights and feelings. We think common courtesy can succeed where coercion is bound to fail.

And maybe, after we have learned peaceful coexistence by talking to each other civilly and sensibly, we can apply the same approach to our many other problems.

Because, after all, this is hardly the most inflammatory question of our time.

Brought to you in the interest of common courtesy by

R.J. Reynolds Tobacco Company

Smoking in public: A radical proposal.

These days the level of social discourse between smokers and non-smokers is approaching that of a tag-team wrestling match.

While some people try to solve this problem through segregation or confrontation, we at R.J. Reynolds have been proposing a more daring solution: greater courtesy.

For these outlandish views we might be called dreamers and cockeyed optimists. But we continue to believe in the power of politeness to change the world.

We can almost imagine how it might begin.

A smoker is about to light a cigarette in public. He pauses in midmatch, suddenly conscious of the non-smoker next to him. Bracing himself for a hostile response, he asks, "Excuse me, do you mind if I smoke?"

The non-smoker is momentarily stunned by this unexpected act of courtesy. She stifles several witty replies that leap to mind; she cannot let his politeness go unchallenged. "I don't mind," she answers, "as long as you don't let your smoke blow in my face."

Her flagrant tolerance puts the smoker on the defensive. But he tries to regain the upper hand. "I'll do my best," he responds. "Let me know if the smoke bothers you."

A deft comeback. But the non-smoker presses her attack: "I will —and thanks for asking." Not to be outdone, the smoker brazenly replies, "Thanks for being so understanding."

An unlikely dialogue? Perhaps. But, who knows? If this sort of thing ever caught on, it might lead to a sudden outbreak of civil decency. Or even escalate into full-scale friendliness.

Common courtesy. It's just crazy enough, it might work.

Brought to you in the interest of common courtesy by

R.J. Reynolds Tobacco Company

The second-hand smokescreen.

For decades, public and private organizations have waged a massive campaign to discourage cigarette smoking. For most of that time, the target of this effort has been the smoker.

Recently, however, the emphasis has undergone a major shift. Today there are scientists who claim that cigarette smoke in the air can actually cause disease in *non-smokers*. We hear a great deal about "second-hand smoke" and "passive smoking."

But is this new approach wholly motivated by concern for the non-smoker, or is it the same old war on smoking in a new guise?

These doubts are raised when we recall statements like the following, by a spokesperson for the American Lung Association:

> Probably the only way we can win a substantial reduction [in smoking] is if we can somehow make it nonacceptable socially....We thought the scare of medical statistics and opinions would produce a major reduction. It really didn't.

Obviously, one way to make smoking "nonacceptable socially" would be to suggest that second-hand smoke could cause disease. So it is not surprising that we are now seeing a flurry of research seeking scientific support for these suggestions.

Many independent experts believe the scientific evidence on passive smoking is questionable. But a zealous group of anti-smokers are using this issue in their campaign against tobacco as if the claims were established scientific fact.

We deplore the actions of those who try to manipulate public opinion through scare tactics. As the late, respected pathologist, Dr. H. Russell Fisher, stated in testimony submitted to a Congressional hearing on passive smoking:

> ...[I]n the absence of any scientific proof of harm from atmospheric tobacco smoke, we are dealing with a social question and not a medical one. In this regard it should be noted that, since fears and phobias can lead to ill health, those who urge policies based on fear and not scientific facts could be making a medical problem out of a social one. This is indeed a strange prospect to see coming from the efforts of members of the medical profession.

We are not ignoring the fact that cigarette smoke can be bothersome to many non-smokers. But we believe this problem is best solved not by governments but by individuals, and not with more rhetoric but more common sense and courtesy.

Of course, if anti-smoking advocates want to work for the abolition of smoking, that is their right. We only wish they would come out from behind their second-hand smokescreen.

R. J. Reynolds Tobacco Company

2025880296

Workplace smoking restrictions: A trend that never was.

Reports in the news media may have given you the impression that restrictive corporate smoking policies are the wave of the future.

But, when the facts are analyzed, the wave shrinks to just a ripple.

Today, most of corporate America continues to rely on the common sense and common courtesy of employees—not on formal policy—to resolve differences arising out of smoking in the workplace.

This is the key finding of a major new survey of America's leading companies. The survey, commissioned by the Tobacco Institute and completed early in 1985, was conducted by the Human Resources Policy Corporation of Los Angeles among the top 1000 service and industrial companies ranked by *Fortune* magazine and *Inc.* magazine's 100 fastest-growing companies.

Only about one-third of the responding companies said they had any official smoking guidelines in effect. Furthermore, the reasons most frequently given centered around common-sense situations where workers dealt with hazardous substances, sensitive equipment or food. And almost half of these policies had been in effect for over five years.

Two-thirds of the companies reported they prefer to encourage individual workers to settle smoking issues with mutual respect for each other's legitimate rights and feelings.

We at R.J. Reynolds think this is not just common sense, but good business. Because it also gives managers the flexibility they need to make decisions in the best interest of the company as a whole.

That's the way it's worked in the past. And we think it's the best blueprint for the future.

R.J. Reynolds Tobacco Company

Of cigarettes and science.

This is the way science is supposed to work.

A scientist observes a certain set of facts. To explain these facts, the scientist comes up with a theory.

Then, to check the validity of the theory, the scientist performs an experiment. If the experiment yields positive results, and is duplicated by other scientists, then the theory is supported. If the experiment produces negative results, the theory is re-examined, modified or discarded.

But, to a scientist, both positive and negative results should be important. Because both produce valuable learning.

Now let's talk about cigarettes.

You probably know about research that links smoking to certain diseases. Coronary heart disease is one of them.

Much of this evidence consists of studies that show a statistical association between smoking and the disease.

But statistics themselves cannot explain *why* smoking and heart disease are associated. Thus, scientists have developed a theory: that heart disease is *caused* by smoking. Then they performed various experiments to check this theory.

We would like to tell you about one of the most important of these experiments.

A little-known study

It was called the Multiple Risk Factor Intervention Trial (MR FIT).

In the words of the *Wall Street Journal*, it was "one of the largest medical experiments ever attempted." Funded by the Federal government, it cost $115,000,000 and took 10 years, ending in 1982.

The subjects were over 12,000 men who were thought to have a high risk of heart disease because of three risk factors that are statistically associated with this disease: smoking, high blood pressure and high cholesterol levels.

Half of the men received no special medical intervention. The other half received medical treatment that consistently reduced all three risk factors, compared with the first group.

It was assumed that the group with lower risk factors would, over time, suffer significantly fewer deaths from heart disease than the higher risk factor group.

But that is not the way it turned out.

After 10 years, there was no statistically significant difference between the two groups in the number of heart disease deaths.

The theory persists

We at R.J. Reynolds do not claim this study proves that smoking doesn't cause heart disease. But we do wish to make a point.

Despite the results of MR FIT and other experiments like it, many scientists have not abandoned or modified their original theory, or re-examined its assumptions.

They continue to believe these factors cause heart disease. But it is important to label their belief accurately. It is an opinion. A judgment. But *not* scientific fact.

We believe in science. That is why we continue to provide funding for independent research into smoking and health.

But we do not believe there should be one set of scientific principles for the whole world, and a different set for experiments involving cigarettes. Science is science. Proof is proof. That is why the controversy over smoking and health remains an open one.

R.J. Reynolds Tobacco Company

SECTION 6 - MRFIT/FTC
COMPLAINT - RESPONSE TO QUERY

2025880299

2025880299

MRFIT/FTC Complaints

On June 17, 1986, the Federal Trade Commission, by a vote of 4 to 1, issued a complaint against R.J. Reynolds Tobacco Company. The complaint alleges the company engaged in unfair and deceptive advertising practices by publishing an issue ad, "Of Cigarettes and Science." FTC chairman Oliver dissented from the complaint saying the company was justified in expressing a point of view in a paid editorial which was unlikely to be articulated elsewhere.

R.J. Reynolds Tobacco Company intends to challenge the FTC's complaint on two grounds: First, the message in question is fully protected under the First Amendment and therefore outside the FTC's jurisdiction. Second, the message was fair and accurate and therefore not "false or deceptive."

In July the administrative law judge hearing the complaint dismissed it saying the advertisement was an editorial protected by freedom of speech laws. Staff members of the FTC have appealed the ruling and written arguments on the appeal are due in mid-October, 1986.

Following are documents intended to provide background on the subject and answer queries:

- FTC complaint and press release.
- News stories and an editorial relating to the complaint.
- Journal of the American Medical Association article on MRFIT.
- Response to query and Q's and A's.

FTC COMPLAINT AND
PRESS RELEASE

2025880301

TO: JIM FYOCK
RJR
(919) 773-2955
FROM: J. BLIZIN, H&K (202) 638-2800

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of R.J. REYNOLDS TOBACCO COMPANY, INC. a corporation.	DOCKET NO. 9206

COMPLAINT

The Federal Trade Commission, having reason to believe that R.J. Reynolds Tobacco Company, Inc., a corporation, (R.J. Reynolds or "respondent") has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

PARAGRAPH ONE: R.J. Reynolds is a New Jersey corporation, with its offices and principal place of business located at 401 North Main Street, Winston-Salem, North Carolina 27101.

PARAGRAPH TWO: Respondent manufactures, advertises, offers for sale, sells and distributes cigarettes and other tobacco products.

PARAGRAPH THREE: The acts and practices of respondent alleged in this complaint have been in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act.

PARAGRAPH FOUR: In the course and conduct of its business, respondent has disseminated or caused the dissemination of an advertisement entitled "Of cigarettes and science," attached hereto as Exhibit A.

2025880302

PARAGRAPH FIVE: In this advertisement respondent has represented, directly or by implication, that:

(a) The Multiple Risk Factor Intervention Trial (the MR FIT study) was designed and performed to test whether cigarette smoking causes coronary heart disease;

(b) A major government study about smoking and coronary heart disease (the MR FIT study) provides credible scientific evidence that smoking is not as hazardous as the public or the reader has been led to believe; and

(c) The MR FIT study, a major government study, tends to refute the theory that smoking causes coronary heart disease.

PARAGRAPH SIX: The representations set forth in PARAGRAPH FIVE are false or misleading.

PARAGRAPH SEVEN: In light of the representations made in the advertisement, and because of the way in which the advertisement describes the MR FIT study and its results, respondent's failure to disclose:

(a) that men in the study who quit smoking had a significantly lower rate of coronary heart disease death than men who continued to smoke; or

(b) that the MR FIT study results are consistent with previous studies showing that those who quit smoking enjoy a substantial decrease in coronary heart disease mortality,

renders the advertisement deceptive.

PARAGRAPH EIGHT: The acts and practices of respondent as alleged in this complaint constitute unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

NOTICE

Notice is hereby given to respondent hereinbefore named that the 28th day of July, 1986 at 10 o'clock is hereby fixed as the time and FTC, 2120 L St., NW, Wash., D.C. 20580 as the place when and where a hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under said Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in this complaint.

You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the thirtieth (30th) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material allegations to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint, and together with the complaint will provide a record basis on which the Administrative Law Judge shall file an initial decision containing appropriate findings and conclusions and an appropriate order disposing of the proceeding. In such answer you may, however, reserve the right to submit proposed findings and conclusions and the right to appeal the initial decision to the Commission under Section 3.52 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to answer within the time above provided shall be deemed to constitute a waiver of your right to appear and contest the allegations of the complaint and shall authorize the Administrative Law Judge, without further notice to you, to find the facts to be as alleged in the complaint and to enter an initial decision containing such findings, appropriate conclusions and order.

The following is the form of order which the Commission has reason to believe should issue if the facts are found to be as alleged in the complaint. If, however, the Commission should conclude from record facts developed in any adjudicative proceedings in this matter that the proposed order provisions as to R.J. Reynolds Tobacco Company, Inc., a corporation, might be inadequate to fully protect the consuming public, the Commission may order such other relief as it finds necessary or appropriate.

ORDER

I.

IT IS ORDERED that respondent, R.J. Reynolds Tobacco Company, Inc., a corporation; its successors and assigns; and its officers, representatives, agents and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, or promotion of cigarettes in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Representing directly or by implication that the MR FIT study was designed and/or performed to test whether cigarette smoking causes coronary heart disease.

B. Representing directly or by implication that the MR FIT study is credible scientific evidence that cigarette smoking is not as hazardous as the public or the reader had been led to believe.

C. Representing directly or by implication that the MR FIT study tends to refute the theory that smoking causes coronary heart disease.

D. Failing to disclose, in any discussion of the MR FIT study that questions the relationship between smoking and smokers' risk of coronary heart disease, that: (a) men in the study who quit smoking had a significantly lower rate of coronary heart disease death than men who continued to smoke; or (b) that the MR FIT study results are consistent with previous studies showing that those who quit smoking enjoy a substantial decrease in coronary heart disease mortality.

E. Misrepresenting in any manner, directly or by implication, the design, purpose, content, or results of any scientific test or study in any discussion of cigarette smoking and health.

II.

IT IS FURTHER ORDERED that respondent shall notify the Commission at least thirty (30) days prior to any proposed change in the corporation such as a dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporation which may affect compliance obligations under this Order.

III.

IT IS FURTHER ORDERED that respondent shall, within sixty (60) days after service of this Order upon it and at such other times as the Commission may require, file with the Commission a written report setting forth in detail the manner and form in which it has complied or intends to comply with this Order.

* * * * *

THEREFORE, the Federal Trade Commission has caused its complaint to be signed by its Secretary and its official seal to be affixed at Washington, D.C. this 16th day of June, 1986.

By the Commission. Chairman Oliver dissented. Commissioner Strenio supported issuance of this complaint but dissented from inclusion of paragraph Seven.

Emily H. Rock
Secretary

SEAL:

Attachment: Separate Statement by Chairman Oliver

Of cigarettes and science.

This is the way science is supposed to work.

A scientist observes a certain set of facts. To explain these facts, the scientist comes up with a theory.

Then, to check the validity of the theory, the scientist performs an experiment. If the experiment yields positive results, and is duplicated by other scientists, then the theory is supported. If the experiment produces negative results, the theory is re-examined, modified or discarded.

But, to a scientist, both positive and negative results should be important. Because both produce valuable learning.

Now let's talk about cigarettes.

You probably know about research that links smoking to certain diseases. Coronary heart disease is one of them.

Much of this evidence consists of studies that show a statistical association between smoking and the disease.

But statistics themselves cannot explain *why* smoking and heart disease are associated. Thus, scientists have developed a theory: that heart disease is *caused* by smoking. Then they performed various experiments to check this theory.

We would like to tell you about one of the most important of these experiments.

A little-known study

It was called the Multiple Risk Factor Intervention Trial (MR FIT).

In the words of the *Wall Street Journal*, it was "one of the largest medical experiments ever attempted." Funded by the Federal government, it cost $115,000,000 and took 10 years, ending in 1982.

The subjects were over 12,000 men who were thought to have a high risk of heart disease because of three risk factors that are statistically associated with this disease: smoking, high blood pressure and high cholesterol levels.

Half of the men received no special medical intervention. The other half received medical treatment that consistently reduced all three risk factors, compared with the first group.

It was assumed that the group with lower risk factors would, over time, suffer significantly fewer deaths from heart disease than the higher risk factor group.

But that is not the way it turned out.

After 10 years, there was *no* statistically significant difference between the two groups in the number of heart disease deaths.

The theory persists

We at R.J. Reynolds do not claim this study proves that smoking doesn't cause heart disease. But we do wish to make a point.

Despite the results of MR FIT and other experiments like it, many scientists have not abandoned or modified their original theory, or re-examined its assumptions.

They continue to believe these factors cause heart disease. But it is important to label their belief accurately. It is an opinion. A judgment. But *not* scientific fact.

We believe in science. That is why we continue to provide funding for independent research into smoking and health.

But we do not believe there should be one set of scientific principles for the whole world, and a different set for experiments involving cigarettes. Science is science. Proof is proof. That is why the controversy over smoking and health remains an open one.

R.J. Reynolds Tobacco Company

DISSENTING STATEMENT BY CHAIRMAN OLIVER

R.J. REYNOLDS TOBACCO CO.

June 16, 1986

I respectfully dissent from the Commission's decision to issue a complaint challenging R.J. Reynolds' paid "editorial" titled "Of Cigarettes and Science." The challenged statement, as I read it, engages an issue that is a subject of public concern, and expresses a point of view that is unlikely to be articulated elsewhere. I believe that, as a matter of public policy, it is valuable for the public to hear all sides of an issue, and I am concerned about taking any action that may inhibit free expression of views that might not be popular to government regulators. Although, after reviewing the evidence presented to the Commission, I cannot conclude that issuance of this complaint is in the public interest, I, of course, express no view on the underlying legal and factual issues raised by this case.

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: June 16, 1986

R. J. REYNOLDS AD ON SMOKING AND HEALTH IS MISLEADING, FTC CHARGES IN COMPLAINT

The Federal Trade Commission charged in an administrative complaint issued today that R. J. Reynolds Tobacco Co. Inc. misrepresented the purpose and results of a major government-funded study in an advertisement.

The ad, titled "Of Cigarettes and Science," ran from March to June 1985 in leading newspapers and magazines, including the Washington Post, the New York Times, Newsweek, and Time.

According to the complaint, the ad made three claims about the study that the FTC alleges are false or misleading:

- that it was designed and performed to test whether cigarette smoking causes heart disease;
- that it provides credible scientific evidence that smoking is not as hazardous as the public or the reader has been led to believe; and
- that it tends to refute the theory that smoking causes heart disease.

In addition, according to the complaint, R. J. Reynolds failed to disclose in the ad that men in the study who quit smoking had a significantly lower rate of death from heart disease than men who continued to smoke or that the study's results are consistent with previous studies showing that those who quit smoking have a substantial decrease in death from heart disease. The complaint charged that in light of the claims made in the ad, the omission of this information made the ad deceptive.

The study discussed in the ad is the Multiple Risk Factor Intervention Trial, referred to as MR FIT, which was funded by the National Heart, Lung and Blood Institute of the National Institutes of Health.

The Commission issues a complaint when it has reason to believe that the law has been or is being violated, and where it appears to the Commission that a proceeding is in the public interest. Such action marks the beginning of a proceeding in which the allegations will be ruled upon after a formal hearing.

If the Commission's allegations are upheld, R. J. Reynolds could be prohibited from misrepresenting in ads discussing cigarette smoking and health the purpose or results of the MR FIT study or any other scientific tests or studies. The company could also be required to disclose the omitted information about death from heart disease in ads that discuss results of the MR FIT study and question the relationship between smoking and smokers' risk of heart disease.

(More)

The vote to issue the complaint was 4-1, with Chairman Daniel Oliver dissenting. Chairman Oliver said in a separate statement, "I believe that, as a matter of public policy, it is valuable for the public to hear all sides of an issue, and I am concerned about taking any action that may inhibit free expression of views that might not be popular to government regulators." Commissioner Andrew J. Strenio Jr. said he supports the issuance of this complaint, but dissents from the inclusion of paragraph seven.

R. J. Reynolds Tobacco Co. Inc., a subsidiary of RJR Nabisco Inc., is one of the major cigarette manufacturers in the United States. It manufactures more than 20 brands of cigarettes and accounts for about one-third of the U.S. cigarette market. R. J. Reynolds is based in Winston-Salem, N.C.

Copies of the complaint and proposed order are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Dee Ellison, Office of Public Affairs, 202-523-1891

STAFF CONTACTS: James H. Skiles, Bureau of Consumer Protection, 202-376-8648

FTC File No. 852 3143

[RJReynolds]

NEWS STORIES/EDITORIALS

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Publication: THE NEW YORK TIMES (Sunday edition)
Date: 7/6/86
Section 3
Page: F-2

R.J. REYNOLDS VS. THE GOVERNMENT

A Chilling Effect on Corporate Speech

Floyd Abrams, a partner with Cahill Gordon & Reindel, is representing R.J. Reynolds in the F.T.C. action.

By FLOYD ABRAMS

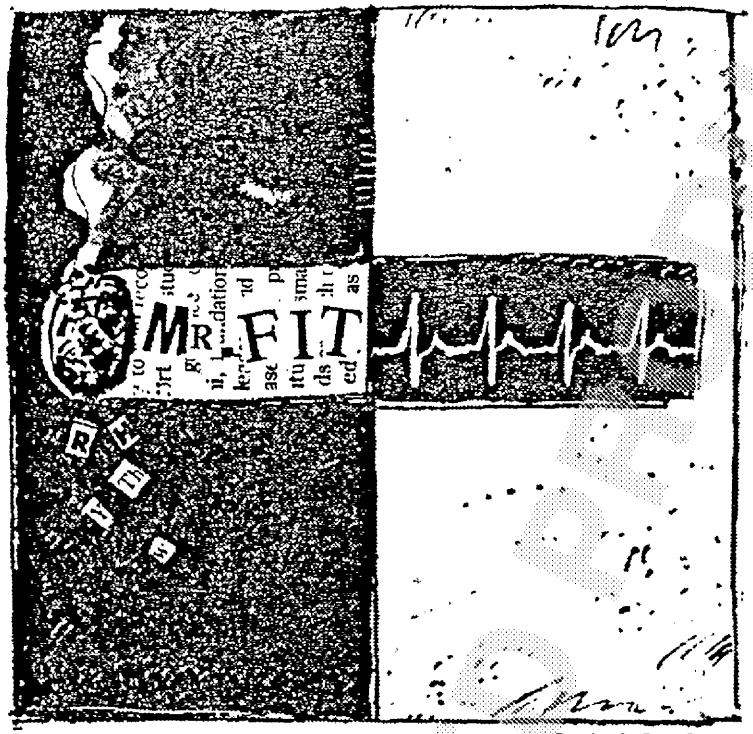
IF ONE thing is common to all First Amendment cases it is this: Someone, somewhere in the Government thinks it better that someone outside the Government not speak as he or she chooses. Sometimes the official tries to prevent the speech. On other occasions, efforts are made to punish the speaker. Whatever form it takes, the theme is the same: rather than answer the speaker, stop the speech.

Governments are not always wrong to be troubled by speech. They are almost always wrong in seeking to suppress it.

So it is with the Federal Trade Commission's complaint against the R.J. Reynolds Tobacco Company arising out of its publication, in this newspaper and elsewhere, of an editorial advertisement last March. Reynolds's message contained not a mention of the brand of any of its cigarettes. It did not urge the purchase of any cigarettes at all. Far from being a sales pitch, the totality of the Reynolds message was an argument, a statement of editorial opposition to what Reynolds views as a double standard in science in which one set of scientific priciples seems to be applied to the whole world and quite a different one to cigarettes.

In Reynolds's view, the use made of the Government's "MRFIT" study was one example of this dual standard. This study was designed to determine whether a reduction in three "risk factors," including cigarette smoking, would reduce deaths related to coronary heart disease. After 10 years and the expenditure of $115 million, the result was a surprise to its sponsors. The study demonstrated no statistically significant decline in the death rates. There is no argument about this.

In Reynolds's opinion, what followed is the crux of the issue. After the fact, the scientific investigators



Drawings by Beata Szpura

searched the data for anything that could justify the study's $115 million cost. What they found was that men who quit smoking during the first year of the study tended to have lower death rates. The investigators, however, stated that no reliable conclusions could be drawn from this finding because such an analysis violated the design of the study and could not be supported by established statistical criteria. Despite this explicit disclaimer, spokesmen for the Federal Government and others focused on this "finding" to support their position that a reduction in cigarette smoking, in and of itself, resulted in lower death rates.

Reynolds expressly stated in its editorial ad that "We at R.J. Reynolds do not claim this study proves that smoking doesn't cause heart disease." Nevertheless, the F.T.C. is now claiming that Reynolds does not have the right to express its views on what it considers a misrepresentation of the results of the MRFIT study.

The message was controversial. It was meant to be. But instead of simply answering it, Reynolds's critics sought to involve the Government in an effort to punish the company for speaking at all. And they succeeded.

The chairman of the F.T.C., Daniel Oliver, understood the real issue at stake. Dissenting from the complaint, he concluded that Reynolds's message "engages an issue that is a subject of public concern, and expresses a point of view that is unlikely to be articulated elsewhere." As a matter of public policy, Chairman Oliver wrote, "it is valuable for the public to hear all sides of an issue, and I am concerned about taking any action that may inhibit free expression of views that may not be popular to Government regulators."

The people, in and out of Government, who wish to punish Reynolds for speaking take a different tack. Because Reynolds is so wrong, they believe, the Government should step in. But the notion that speech on public issues may be regulated by Government is inconsistent with the most well-established First Amendment principles.

Of course, the Government should not be without power to regulate advertisements that, unlike the Reynolds ad, propose commercial transactions. That power the F.T.C. has always had and continues to have. But, as the Supreme Court has consistently concluded, what no Government agency can regulate is discussion about matters of public concern and the expression of opinions about those matters — even in an editorial advertisement. This is what the Reynolds case is about.

There is an additional element in the case. Corporations can play a significant role by expressing their opinions on matters of public controversy. By publicly offering its own views for public discussion, particularly when those views are so rarely heard, Reynolds behaved in just the manner contemplated by the First Amendment. That does not mean that Reynolds's views were unarguably correct. It does mean that if individuals or organizations believed Reynolds was wrong, they should have answered. It means that if the Government believed Reynolds was wrong, it could have answered. On no account is there any excuse for silencing Reynolds.

Corporate speech is peculiarly subject to being chilled, not because corporations are poor or defenseless but because it is so easy for them to spend their money elsewhere than on editorial advertisements. Such expressions of opinion are always controversial. For many corporations, that controversy alone is reason enough to choose silence. For most others, the prospect of a bruising battle with the F.T.C. is ample reason to devote resources to product advertisements rather than editorial commentary. The public is hardly served by such a choice. ■

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Business Can Speak Out in Other Ways

Matthew Myers is staff director of the Coalition on Smoking or Health, an advocacy group.

By MATTHEW MYERS

LATE last month, in the most important challenge to tobacco industry advertising in 25 years, the Federal Trade Commission sued the R. J. Reynolds Tobacco Company for violating the Federal prohibition against false and deceptive advertising in an ad entitled "Of Cigarettes and Science." The commission properly charged that the ad, which disputes the scientific evidence linking cigarette smoking to heart disease, was nothing more than a blatant attempt by R. J. Reynolds to increase overall cigarette sales by deceptively downplaying the relationship between cigarette smoking and cardiovascular disease.

In the advertisement, which ran in at least 25 newspapers and magazines beginning in March 1985, Reynolds directly, or by implication, made three false claims.

First, the ad claimed that, as of 1972, scientists believed that the evidence that smoking causes heart disease was so speculative that a new study was needed to test this unproven theory. The study was called the Multiple Risk Factor Intervention Trial (MRFIT).

Second, the ad claimed that the results of MRFIT were inconsistent with the conclusion that smoking causes heart disease.

Third, the ad claimed that the results of MRFIT should have caused objective scientists to abandon or modify their prior conclusions about smoking and heart disease.

The F.T.C. charged Reynolds with seriously misrepresenting the purpose, findings and conclusions of the MRFIT study and with failing to disclose that, contrary to the representations in the ad, the most important finding in the study with regard to smoking reaffirmed the link between smoking and heart disease.

A brief examination of the facts demonstrates the merit of the F.T.C.'s position. There has been no credible scientific controversy about the health effects of smoking for more than 20 years. By 1979, the Surgeon General reported that "there was no longer any doubt that cigarette smoking was directly related to coronary heart disease."

The MRFIT study was not designed to test the link between smoking and heart disease. This was because the scientists who designed MRFIT believed the scientific evidence on that issue to be beyond question. The study was designed solely to test whether aggressive treatment could lower the rates of heart attack for men who suffered from a combination of high blood pressure, high cholesterol levels and smoking.

In the study, the men were divided into two groups — one for special care and the other for "usual" care by their personal doctors. After 10 years, there was no statistically significant difference in the coronary death rates of the two groups. What happened was that the men in both groups reduced all the risk factors for heart disease, including smoking.

The key finding with regard to smoking was that, in either group, those who quit smoking reduced their coronary death rate by nearly 50 percent, a fact not mentioned by Reynolds. Thus, there can be little doubt that "Of Cigarettes and Science" is a disturbing, and in all likelihood, deliberate distortion.

WHAT IS R. J. Reynolds's response? It claims that the F.T.C.'s action threatens its "freedom of speech," and that the First Amendment provides absolute protection to ads such as "Of Cigarettes and Science," as part of a corporation's right to express its opinion on matters of public controversy, no matter how inaccurate the ad. Reynolds's position is seriously flawed.

First, Reynolds remains free to express its views about smoking and health. The F.T.C. has said only that, when a tobacco company purchases advertising space to describe scientific findings concerning smoking and health, it must do so in a manner that is not false and misleading. Reynolds's First Amendment defense amounts to a thinly-veiled claim of a right to lie about the health hazards of the cigarettes it sells. No such right exists, nor should it exist.

As the Supreme Court has held repeatedly, the First Amendment provides no protection from false and deceptive commercial speech. If the F.T.C. prevails, Reynolds will remain free to speak out as often and as loud as it wishes; it just must do so honestly and accurately.

Second, the company tries to disguise this clearly commercial effort by putting its ad into the format of a newspaper editorial or op-ed piece, simply to expand its First Amendment protection. This charade does not alter the essential commercial character of this ad. To avoid just such a charade, the Supreme Court has explicitly held that advertisers may not immunize false or misleading product information by including references to public issues or by altering their ad's format.

Who does R.J. Reynolds think it is kidding when it claims that its sole interest is in fostering public debate? By creating a scientific controversy where none exists and by falsely casting doubt on the relationship between smoking and heart disease, Reynolds has only one goal: to sell more cigarettes. Profits, not public debate, are at the heart of this advertisement.

There are no serious First Amendment issues at stake here. What is at stake is the right of the public not to be misled about this nation's No. 1 preventable cause of death by a company looking to increase its sales. ■

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END
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TO: JIM PYLE RJ REYNOLDS

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FTC Complaint Says Reynolds Tobacco Ad Misled the Public

E1

By Martha M. Hamilton
Washington Post Staff Writer

The Federal Trade Commission charged yesterday that R. J. Reynolds Tobacco Co. Inc. misled the public with an advertisement that the agency said downplayed the relationship between heart disease and smoking.

In an administrative complaint filed yesterday, the FTC said that the ad misrepresented the purpose and results of a government-funded research study by suggesting that the study tended to refute the theory that smoking causes heart disease and that the ad left out information that suggested a link between smoking and heart disease.

For instance, the ad failed to mention that men in the study who quit smoking had a significantly lower rate of coronary heart disease deaths than men who continued to smoke, according to the FTC.

The advertisement, titled "Of cigarettes and science," appeared in a number of major newspapers and magazines, including The Washington Post, The New York Times, Newsweek and Time, in March and June 1985.

The tobacco company, an RJR Nabisco Inc. subsidiary, accounts for about one-third of the cigarettes sold in the United States. R. J. Reynolds said it would challenge the FTC's action, labeling it an attack on free speech and the First Amendment.

The FTC voted 4 to 1 to issue the complaint. The agency's new chairman, Daniel Oliver, dissented. Oliver's arguments were similar to the company's.

"I believe that, as a matter of public policy, it is valuable for the public to hear all sides of an issue, and I am concerned about taking any action that may inhibit free expression of views that might not be popular to government regulators," he said.

"We at R. J. Reynolds do not claim this study proves that smoking doesn't cause heart disease," the ad stated. But it went on to say that "the controversy over smoking and health remains an open one."

The FTC said that the advertisement misled readers by suggesting that the study in question, the Multiple Risk Factor Intervention Trial, was designed and performed to test whether cigarette smoking causes coronary heart disease and that it provided credible scientific evidence that smoking is not as hazardous as the public or the reader had been led to believe.

The ad also failed to disclose that the results of the study "are consistent with previous studies showing that those who quit smoking enjoy a substantial decrease in coronary heart disease mortality," the FTC said.

If the complaint is upheld, the tobacco company could be barred from misrepresenting the results of the study or other research in future advertising or could be required to disclose the information about death from heart disease that the FTC said the advertising should have contained.

"The message in question was a fair and accurate commentary providing R. J. Reynolds Tobacco Co.'s opinion on one aspect of a significant public controversy: the smoking and health issue," a company spokesman said. The company has retained prominent First Amendment attorney Floyd Abrams to represent it in its challenge to the FTC action.

"The key issue at stake in this proceeding before the Federal Trade Commission is the right of a company to comment on important public matters," according to a statement prepared by Reynolds. "This proceeding by the FTC poses a serious threat to the freedom of speech of companies and individuals alike."

Abrams said that the Reynolds ad was similar to an editorial or an "op-ed" piece in a newspaper. "It was not a cigarette ad. It was an editorial ad," he said. "It seems to me a clear and unambiguous violation of the First Amendment for the FTC to commence this action. If the commission does not conclude that its complaint violates the First Amendment, the courts will."

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Washington Post
6/17/86 E1

FTC CHARGES R.J. REYNOLDS
AD MISREPRESENTED STUDY

WASHINGTON -DJ- THE FTC CHARGED THAT R.J. REYNOLDS TOBACCO, NOW A UNIT OF RJR NABISCO INC., MISREPRESENTED IN A NEWSPAPER AND MAGAZINE ADVERTISEMENT THE PURPOSE AND RESULTS OF A GOVERNMENT STUDY ON CIGARETTES AND HEALTH.

THE AD, ENTITLED ''OF CIGARETTES AND SCIENCE,'' RAN FROM MARCH TO JUNE 1985 IN PUBLICATIONS INCLUDING THE WASHINGTON POST, THE NEW YORK TIMES AND NEWSWEEK AND TIME MAGAZINES.

ACCORDING TO THE FTC COMPLAINT, THE AD MADE THREE FALSE CLAIMS AND OMITTED IMPORTANT INFORMATION.

THE FTC SAID THE ALLEGEDLY FALSE CLAIMS INCLUDED AN ASSERTION THAT THE STUDY WAS DESIGNED AND PERFORMED TO TEST WHETHER CIGARETTE SMOKING CAUSES HEART DISEASE; AN ASSERTION THAT THE STUDY PROVIDED SCIENTIFIC EVIDENCE THAT SMOKING ISN'T AS HAZARDOUS AS THE PUBLIC HAS BEEN LED TO BELIEVE, AND AN ASSERTION THAT THE STUDY TENDS TO REFUTE THE THEORY THAT SMOKING CAUSES HEART DISEASE.

THE FTC ALSO CHARGED THAT REYNOLDS FAILED TO DISCLOSE IN THE AD THAT MEN IN THE STUDY WHO QUIT SMOKING HAD A SIGNIFICANTLY LOWER DEATH RATE FROM HEART DISEASE THAN MEN WHO CONTINUED TO SMOKE.

THE STUDY DISCUSSED IN THE AD IS THE ''MULTIPLE RISK FACTOR INTERVENTION TRIAL,'' REFERRED TO AS THE ''MR FIT TRIAL,'' WHICH WAS FUNDED BY THE NATIONAL HEART, LUNG & BLOOD INSTITUTE OF THE NATIONAL INSTITUTES OF HEALTH.

IF THE FTC CHARGES ARE UPHELD IN ADMINISTRATIVE LAW PROCEEDINGS, REYNOLDS COULD BE PROHIBITED FROM MISREPRESENTING THIS STUDY OR ANY OTHER SCIENTIFIC TESTS OR STUDIES IN ADS DISCUSSING CIGARETTE SMOKING AND HEALTH. THE COMPANY ALSO COULD BE REQUIRED TO DISCLOSE THE INFORMATION OMITTED FROM THE AD.

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Dow Jones

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THE NEW YORK TIMES, THURSDAY, JUNE 19, 1986

'Facts' About Smoking

If all the R.J. Reynolds Tobacco Company had done was what its competitors do — use advertising to imply that cigarette smoking makes one sexier, handsomer, prettier, manlier and, oh yes, more liberated — it wouldn't be in trouble with the Federal Trade Commission.

But Reynolds forsook image for "facts" last year with an ad that, the F.T.C. contends, misrepresented a 10-year study financed by the National Institutes of Health. The Commission charges the company with violating Federal prohibitions against "unfair or deceptive" advertising.

The "MR FIT" (Multiple Risk Factor Intervention Trial) study involved more than 12,000 men thought to be at risk of heart disease because they had high blood pressure, high cholesterol levels and smoked cigarettes. Half the men were given normal medical care; the rest received special diet, treatment for hypertension and counseling to stop smoking. After 10 years, the number of deaths from heart disease in each group did not differ significantly. But in both groups, the death rate from heart disease for men who had quit smoking was 50 percent lower than for those who had not.

The Reynolds ad, published in The Times and elsewhere, said the study was designed to test the theory that smoking causes heart disease. It was not, as "multiple risk factors" denotes. But it was what the ad did not say that provoked the F.T.C. to call it "deceptive."

By not disclosing the disparity in the death rate between those who stopped smoking and those who didn't, Reynolds implied that the MR FIT study failed to establish a link between smoking and heart disease. It described a belief in such a link as "an opinion. A judgment. But not scientific fact." Furthermore, the ad continued, "the controversy over smoking and health remains an open one." It does not: the study is one of many with similar findings.

David B. Fishel, a vice president of the tobacco company, says the F.T.C. charge "poses a serious threat to the freedom of speech of companies and individuals alike." Fortunately, the issue to be decided here is factual, not constitutional. Heaven forfend laws to prevent a cosmetics manufacturer from contending that a new lipstick will change a woman's life or a new after-shave a man's. But in law and decency, scientific findings should have to be rendered scrupulously, particularly in matters of life and death.

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JAMA
THE JOURNAL of the American Medical Association
Sept 24, 1982 Vol 248, No 12

Original Contributions

Multiple Risk Factor Intervention Trial

Risk Factor Changes and Mortality Results

Multiple Risk Factor Intervention Trial Research Group

• The Multiple Risk Factor Intervention Trial was a randomized primary prevention trial to test the effect of a multifactor intervention program on mortality from coronary heart disease (CHD) in 12,866 high-risk men aged 35 to 57 years. Men were randomly assigned either to a special intervention (SI) program consisting of stepped-care treatment for hypertension, counseling for cigarette smoking, and dietary advice for lowering blood cholesterol levels, or to their usual sources of health care in the community (UC). Over an average follow-up period of seven years, risk factor levels declined in both groups, but to a greater degree for the SI men. Mortality from CHD was 17.9 deaths per 1,000 in the SI group and 19.3 per 1,000 in the UC group, a statistically nonsignificant difference of 7.1% (90% confidence interval, −15% to 25%). Total mortality rates were 41.2 per 1,000 (SI) and 40.4 per 1,000 (UC). Three possible explanations for these findings are considered: (1) the overall intervention program, under these circumstances, does not affect CHD mortality; (2) the intervention used does affect CHD mortality, but the benefit was not observed in this trial of seven years' average duration, with lower-than-expected mortality and with considerable risk factor change in the UC group; and (3) measures to reduce cigarette smoking and to lower blood cholesterol levels may have reduced CHD mortality within subgroups of the SI cohort, with a possibly unfavorable response to antihypertensive drug therapy in certain but not all hypertensive subjects. This last possibility was considered most likely, needs further investigation, and lends support to some preventive measures while requiring reassessment of others.

(*JAMA* 1982;248:1465-1477)

BACKGROUND

THE YEARS subsequent to World War II saw increasing evidence of the importance of arteriosclerosis and its complications as the leading cause of death in the United States. Scientific studies in the laboratory, clinic, and in population groups pointed to the contributing roles of diet, hypertension, cigarette smoking, diabetes, and other risk factors in the genesis of coronary heart disease (CHD). Yet convincing demonstrations of the favorable effect of risk factor modification on CHD morbidity and mortality were not at hand by the 1960s.

For editorial comment see p 1501.

In July 1970, the National Heart and Lung Institute (NHLI) convened a Task Force on Arteriosclerosis specifically to develop a broad long-range plan for the study, control, and possible prevention of arteriosclerosis.[1] The Task Force concluded that the time had come for vigorous application of existing knowledge for the purpose of determining whether CHD could be prevented. Among its final recommendations were (1) the advice not to institute a large-scale national diet-heart trial because of excessive cost and uncertain feasibility, and (2) a proposal that multiple risk factor intervention trials be undertaken to ascertain whether modification of elevated serum cholesterol levels, hypertension, and cigarette smoking in persons at increased risk of death from heart attacks would result in reduction of coronary death rates. With acceptance of the latter proposal, the NHLI prepared and distributed requests for participation of clinical and support centers in the Multiple Risk Factor Intervention Trial (MRFIT).

METHODS

Organization

In 1972 and 1973, awards from the NHLI (later the National Heart, Lung, and Blood Institute, or NHLBI) were made to 22 clinical centers, a coordinating center, a laboratory center, a laboratory standardization center, and two electrocardiography centers. A policy advisory board, whose members had no formal association with any of the other participating units of the trial, was appointed by the Institute to provide advice on the overall course of the trial and to monitor the effects of intervention.[2] A steering committee comprised of investigators from the clinical and support centers and NHLBI staff was responsible for the scientific leadership of the trial.[2]

Design

The MRFIT design called for the recruitment of at least 12,000 men aged 35 to 57 years who were at increased risk of

From the Multiple Risk Factor Intervention Trial Research Group sponsored by the National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, Md.

Reprint requests to MRFIT Coordinating Center, Biometry Division, University of Minnesota, School of Public Health, Room 508, 2829 University Ave SE, Minneapolis, MN 55414 (Marcus O. Kjelsberg, PhD).

death from CHD, but had no clinical evidence of CHD. Persons were designated at "increased risk" if their levels of three risk factors—cigarette smoking, serum cholesterol, and blood pressure (BP)—were sufficiently high at a first screening visit to place them in the upper 15% of a risk score distribution based on data from the Framingham Heart Study.[7] After about one third of the screening was completed and success in recruitment had been demonstrated, the 15% was changed to 10% to increase the average risk level of the eligible men. As an example of the application of this criterion, a man whose diastolic BP was 90 mm Hg and who reported smoking 30 cigarettes per day was risk-eligible at the 10% level if his serum cholesterol level was at least 295 mg/dL. The study was restricted to men because of their much higher risk of premature heart attack compared with women.

The men were to be randomized into two groups of approximately equal size. One group received a "special intervention" (SI) program aimed at cessation of cigarette smoking and reduction of elevated serum cholesterol and BP levels. Men in the other group, "usual care" (UC), were referred to their personal physicians or other community medical facility for such treatment of their risk factors as was considered individually appropriate.

Recruitment

As a first step in identifying at least 12,000 men eligible for the trial, 361,662 men were recruited for a first screening visit to determine CHD risk eligibility and to apply several exclusion criteria. Various recruitment techniques were used, with the most common procedure being to offer voluntary screening to industry or government employee groups. The number recruited for screening at each center ranged from 11,435 to 30,465. The men were informed at the first as well as at subsequent screening visits of the randomized nature of the trial.

Eligibility Criteria

Eligibility was determined at three successive screening visits (S_1, S_2, and S_3). At S_1, to determine risk for CHD, systolic and diastolic BPs were measured, the number of cigarettes smoked daily was ascertained, and a sample of blood was drawn for determination of the serum cholesterol level. Men were excluded from further screening on the basis of low risk, history of a heart attack, diabetes mellitus requiring medication, expected geographic mobility, a serum cholesterol level of 350 mg/dL or higher, or diastolic BP of 115 mm Hg or higher. The last two exclusions were made because of their special clinical features and therapeutic requirements. Of the men seen at S_1, 88,845 (7.1%) qualified and were invited to return for S_2.

The second screening visit, S_2, followed a 12-hour fast and included among other tests (1) a medical history and physical examination; (2) four BP determinations; (3) a locally read resting ECG; (4) a fasting blood sample for measurement of cholesterol, triglyceride, lipoprotein cholesterol, serum thiocyanate, and potassium levels, as well as a blood sample drawn one hour after a 75-g glucose load; (5) pulmonary function tests; (6) a posterior-anterior chest film; (7) an assessment of willingness and ability to adhere to the proposed intervention program; and (8) a detailed explanation of the purposes of the trial and requirements for participation.

Reasons for excluding men at this visit included body weight greater than or equal to 150% of desirable weight; angina pectoris as determined by the Rose questionnaire[8]; history or ECG evidence of myocardial infarction; untreated symptomatic diabetes; diets incompatible with the MRFIT food pattern; treatment with guanethidine, hydralazine, insulin, oral hypoglycemic agents, or lipid-lowering agents; illnesses or disabilities likely to impair full participation in the trial; and diastolic BP of 120 mm Hg or higher. Of the 22,080 men seen at the S_2 visit, 15,791 men (71.5%) were invited to return for the third and final screening visit.

The third screening visit, S_3, included (1) a resting and exercise ECG, (2) a detailed smoking questionnaire, and (3) a 24-hour dietary recall. A brief medical review and examination determined whether any major change in cardiovascular status had occurred since S_2. The purpose and scope of the trial were again explained, and men who then signed the consent form were randomized by the coordinating center into either the SI or UC group. The randomization assignment was obtained by the local clinic coordinator who telephoned the coordinating center after eligibility and willingness to enter the trial had been established. Allocation to SI or UC was stratified by clinic and balanced in blocks of four or six, providing two groups of nearly equal size at each clinic, with 6,428 assigned studywide to SI and 6,438 to UC. Of the 14,111 men seen at S_3, 12,866 were randomized into the trial, constituting a yield of 3.6% of men seen at S_1. The first man was randomized in December 1973; the last randomization occurred on Feb 28, 1976.

Intervention Program

No intervention program was offered to the UC men who continued to be followed by their usual source of medical care, but they were invited to return once a year for a medical history, physical examination, and laboratory studies as listed herein. The results of the screening and annual examinations were provided to their personal physicians, who were informed as to the scientific objectives of the study.

The detailed components of the SI program have been reported earlier[9] and are summarized here. The initial phase of intervention was an intensive integrated effort to lower the three major risk factors. Immediately after randomization to the SI group, each cigarette smoker was counseled individually by a study physician in an effort to achieve cessation of smoking at that time. Shortly thereafter, each SI man was invited with his spouse or friend to a series of weekly group discussions addressing all three risk factors; uniformity of structure and content was sought by the use of common protocols and educational materials. Each group included about ten men and met for about ten sessions.

After the initial intensive intervention phase, individual counseling, planned and executed by an intervention team usually headed by a behavioral scientist and including nutritionists, nurses, physicians, and general health counselors, became the general approach in all three modalities. Participants in the SI group were seen every four months, and more often as needed for intervention purposes. The course of every SI participant was monitored to assess changes in risk factor status, the ultimate objective being to reach specific goals established for each individual.

Hypertension.—Hypertension was considered present if the man reported having antihypertensive medication prescribed for him by his personal physician (regardless of BP level), or if an untreated man was found to have a diastolic BP of at least 90 mm Hg on two consecutive monthly visits during the trial. The reading at the second of these visits was used to establish a goal BP of either a 10 mm Hg reduction or 89 mm Hg, whichever was lower; men who had a diastolic BP of 90 mm Hg or less who were already taking antihypertensive drugs prescribed by a personal physician were assigned a goal of 80 mm Hg. Before drug prescription, weight reduction was attempted for overweight men. Drugs were prescribed according to a stepped-care protocol beginning with the use of either hydrochlorothiazide or chlorthalidone. Reserpine, hydralazine, guanethidine, or certain alternate drugs were sequentially added if goal BP had not been achieved.[9] The protocol also included a provision for mild sodium restriction. Participants in the SI group who had been treated with BP medication by nonstudy physicians were usually transferred, with the permission of their private physicians, to the care of an MRFIT clinician.

Nutrition.—The nutrition intervention program sought to encourage the development of lifelong shopping, cooking, and eating patterns rather than to specify a

structured diet.[7] Individual intervention goals for lowering serum cholesterol levels by an amount dependent on the entry level were established. Initially, eating patterns were recommended that reduced saturated fat intake to less than 10% of calories and dietary cholesterol intake to less than 300 mg/day, and increased polyunsaturated fat intake to 10% of calories. In 1976, the nutrition pattern was changed to specify that saturated fat be less than 8% of calories and dietary cholesterol less than 250 mg/day. Weight reduction was sought for men whose weight was 115% or greater of desirable weight by recommending reductions in caloric intake and increases in moderate forms of physical activity.

Smoking.—The smoking intervention program urged those SI participants who smoked cigarettes to quit; no systematic effort was made to alter the smoking habits of persons who smoked only pipes and cigars.[8] Dosage reduction, including switching to cigarettes low in tar and nicotine, was recommended only as an intermediate step to cessation. Conventional behavioral modification techniques were used throughout the trial; aversive techniques and hypnosis were used in selected instances during the final years. Particularly successful intervention approaches were the ten-week group sessions at the beginning of the trial and the five-day quit clinics during the final years.

Data Collection Methods

On or about each anniversary of randomization, participants in both the SI and UC groups returned for assessment of risk factor levels and morbidity status. Data collected at these annual visits, at screening, intervention, and four-month visits were sent to the coordinating center for processing and analysis. Serum cholesterol concentration obtained at S_1, the first screening visit, for risk eligibility purposes was determined at one of 14 local laboratories established for this purpose and monitored by the Centers for Disease Control (CDC) Lipid Standardization Laboratory and the coordinating center. All subsequent analyses of blood samples for levels of cholesterol, triglycerides, lipoproteins, creatinine, potassium, glucose, uric acid, SGOT, and thiocyanate were determined by the central laboratory using techniques previously described.[9-11]

Except for the ECG taken at S_1 and read locally for exclusion purposes, cassette tapes of all ECGs were sent to the ECG Center in Halifax, Nova Scotia, for computer processing and interpretation. A paper tracing produced from the cassette was then forwarded to the ECG Reading Center in Minneapolis for visual classification according to the Minnesota code. Major ECG abnormalities included major Q wave findings, ST segment elevations and depressions, negative T waves, frequent ventricular premature beats (VPBs) (≥10% of recorded beats), complete atrioventricular (AV) and bundle-branch block, and supraventricular tachycardia. Minor ECG abnormalities included high R waves, left axis deviation, and less frequent VPBs (<10% of recorded beats). The treadmill exercise test at S_1 was done according to a modified Bruce protocol.[12]

Cigarette smoking was measured in two ways: (1) a participant interview for smoking behavior; and (2) thiocyanate-adjusted smoking and quit rates using serum thiocyanate level as an objective measure of smoking behavior.[13]

For analyses in this report, baseline BP is defined as the average of the two random-zero manometer readings at S_1 and S_2; BP at each follow-up visit is the average of the two random-zero readings at the visit. A participant was considered hypertensive at entry if his baseline diastolic BP was 90 mm Hg or higher or if he reported at S_1 having antihypertensive drugs prescribed for him. No attempt was made before randomization to alter antihypertensive medication for those already receiving such agents.

Serum cholesterol concentration was determined at S_1 and each annual follow-up visit using automated methods with periodic quality control developed by the CDC Lipid Standardization Laboratory.[11] Plasma cholesterol and triglyceride concentrations were obtained at S_1 and each annual visit except at 12 months. The cholesterol content of each lipoprotein fraction, estimated after heparin/manganese precipitation, was obtained at S_1 and at 24, 48, and 72 months.[14] All lipid determinations were performed on serum or plasma specimens collected after an overnight fast except for the serum cholesterol at the first screening visit.

Twenty-four hour dietary recalls were obtained at S_1 and at 12, 24, 36, 60 (SI men only), and 72-month visits through interview by an MRFIT nutritionist. Recalls were coded by a Nutrition Coding Center (NCC) with nutrient calculations made using version VI of the NCC food table.[15]

Sample Size and Statistical Power

In planning for the MRFIT, four key endpoints were identified: (1) death from CHD (the primary endpoint); (2) death from cardiovascular disease (CVD); (3) death from any cause; and (4) the combination of fatal CHD and nonfatal myocardial infarction. Data on the first three endpoints are presented in this report on mortality; morbidity data will be included in a subsequent report. Application of the logistic function with coefficients estimated from Framingham data to the observed risk factor combinations of the men randomized projected a six-year CHD death rate for UC men of 29.0 deaths per thousand men. With a sample size of 12,866 (the number eventually randomized into the trial), a reduction in CHD mortality among SI men to 21.3 per thousand (26.6% reduction) could be detected with a probability of .78 using a one-sided test for a difference in proportions at a .05 level of significance. This reduction was determined by using the following anticipated intervention effects (and corresponding potential risk reductions): (1) a 10% reduction of serum cholesterol level if 220 mg/dL or higher—otherwise no change; (2) a 10% reduction of diastolic BP if 95 mm Hg or higher—otherwise no change; and (3) graded reductions in cigarette smoking as follows: 25% reduction for smokers of 40 or more cigarettes per day, 40% for smokers of 20 to 39 per day, and 55% for smokers of less than 20 per day. These anticipated differential intervention effects were based on experience in earlier smoking cessation programs.[16]

In addition, it was assumed that the corresponding groups of UC smokers at entry would have reductions during the course of the trial of 5%, 10%, and 15%, respectively, but that there would be no change in serum cholesterol or BP level in the UC group. Further allowances were incorporated for nonadherence by SI men (estimated to increase progressively to 50% by the end of six years), and for time to achieve maximum potential benefit of risk factor change (estimated to be a "lag" of three years). A similar calculation for the endpoint of death from any cause gave an estimate of power of .92. Statistical aspects of the design have been reported elsewhere.[17]

During the trial, subgroup hypotheses relative to mortality outcome were formulated by MRFIT investigators blinded to interim mortality data with the realization that power would be lower for their testing than for comparisons based on all SI and UC men. These hypotheses were based on the recognition that, in such a group of men at increased risk of coronary disease, a proportion would have advanced coronary atherosclerosis at entry even after excluding those with clinical evidence of CHD (history of myocardial infarction or angina, or ECG evidence of myocardial infarction). One of these hypotheses, that the intervention program would be especially effective in lowering CHD mortality for men with normal baseline resting ECGs, is referred to in this article.

Mortality Ascertainment

All participants were followed for a minimum of six years, with an average period of observation of seven years. Deaths were ascertained by clinic staff through contact with family or friends of the deceased, routine follow-up of missed clinic visits, response to postcards request-

Table 1.—Mean Values of Selected Variables at Entry for MRFIT SI and UC Men*

	SI (n=6,428)	UC (n=6,438)
Screen 1		
Age, yr	48.2	48.1
Serum cholesterol, mg/dL	253.8	253.5
Diastolic BP, mm Hg	99.2	99.2
Cigarette smokers, %	63.8	63.5
Cigarettes smoked by smokers, No. per day	33.7	34.2
Black participants, %	7.2	7.2
Framingham 6-yr risk of CHD death, %	3.12	3.15
Screen 2		
Plasma cholesterol, mg/dL	240.3	240.6
Plasma LDL cholesterol, mg/dL	159.8	160.3
Plasma HDL cholesterol, mg/dL	42.0	42.1
Plasma triglycerides, mg/dL	194.7	193.9
Weight, lb	189.3	189.1
Serum thiocyanate, μmole/L	131.0	131.1
Screen 3		
Minnesota codes 1.1-1.2.7 (definite myocardial infarction), %†	0.36	0.36
Minnesota codes 1.1-1.3 (definite or possible myocardial infarction), %	1.29	1.57
Major ECG abnormalities, %‡	4.4	4.6
Major or minor ECG abnormalities, %	28.4	27.8
Ischemic response to exercise, %§	12.5	11.9
Dietary data (24-hr recall)		
Energy, kcal	2,497	2,478
Saturated fatty acids, % of calories	14.0	14.0
Polyunsaturated fatty acids, % of calories	6.4	6.4
Alcohol, % of calories	7.3	7.6
Cholesterol, mg	458	448
Baseline		
Systolic BP, mm Hg	135.7	135.5
Diastolic BP, mm Hg	91.0	90.9
Hypertensive (baseline diastolic BP ≥90 mm Hg or on antihypertensive drugs at screen 2), %	62.5	63.0

*MRFIT indicates Multiple Risk Factor Intervention Trial Research Group; SI, special intervention; UC, usual care; CHD, coronary heart disease; LDL, low-density lipoprotein; HDL, high-density lipoprotein.

†These men, who had been judged free of ECG evidence of myocardial infarction by clinic physicians in order to be eligible for randomization, were subsequently assigned these Minnesota codes by the ECG Center.

‡For detailed listing of Minnesota codes, see Table 7.

§Based on computer measurement of the ST depression integral.

ing change-of-address information sent twice yearly to UC participants, and searches of publicly accessible files of deceased persons.

To determine survival status as of Feb 28, 1982 (six years after the last day of randomization), a telephone or mail contact was attempted with each man not previously known to be deceased. The status of men not located by this procedure was sought using the files of the Social Security Administration and the service of a commercial firm specializing in methods of follow-up. The 15 SI and 15 UC men whose survival status remained unknown as of July 1, 1982, are included in the analyses as survivors to Feb 28, 1982.

Cause of death was assigned by a Mortality Review Committee, a three-member panel of cardiologists not associated with any MRFIT center and not privy to interim trial results. This committee, without knowledge of study group membership of the deceased, reviewed clinic records, hospital records, next-of-kin interviews, death certificates, and reports of autopsies performed (31% of SI decedents, 33% of UC). Deaths ascribed to CHD were subclassified as (1) myocardial infarction (documented by clinical or autopsy evidence), with death occurring within 30 days of onset of symptoms or during hospitalization for acute myocardial infarction; (2) sudden death (within 24 hours of symptom onset and without documented myocardial infarction); (3) congestive heart failure due to CHD; or (4) death during hospitalization for surgery for CHD or from complications of such an operation.

Statistical Methods

Differences in baseline characteristics and in risk factor levels at annual follow-up visits between men randomly allocated to the SI and UC groups were tested for statistical significance using Student's t (two-sided) or the 2×2 χ^2 test without adjustment for multiple comparisons.

Risk factor changes over time are presented as mean values for all participants who attended each visit. (Results based on cohort analysis and data imputation procedures for missing values, such as substitution of either baseline or previous annual visit risk factor levels, did not differ from those in any substantial way.) Mortality results are presented as life-table functions using the Kaplan-Meier product limit method[9] and as the proportion of deaths as of Feb 28, 1982, among SI and UC participants. Significance testing of mortality results is limited to the key endpoints for the entire cohort. For the three key mortality endpoints, differences between all SI and UC participants are summarized using the log rank test.[10] For the primary endpoint of CHD death, a 90% confidence interval (CI) for the percentage difference,[11] ([UC−SI]/UC)×100, between all SI and all UC men in the proportion of deaths at the end of follow-up is given since the design of the trial was based on a one-sided test at the .05 probability level. For other comparisons, the more conventional 95% CI for the percentage difference is given.

The analysis of subgroups of men is, unless otherwise noted, restricted to groups defined by baseline characteristics. Men are classified, regardless of degree of adherence, as SI or UC based on the allocation at randomization.

RESULTS

Comparison of SI and UC Groups at Entry

The effectiveness of the randomization process in establishing two comparable groups at baseline is demonstrated by the excellent agreement in prerandomization levels of numerous risk factor and risk factor-related variables (Table 1). None of these differences is statistically significant at the .05 level.

Follow-up Visit Record

The missed visit rates (the number of men alive at the time of the specified annual visit but who did not attend, divided by the number of men randomized) were 4.5% for SI and 5.2% for UC men at 12 months; these increased only slightly each year and, although somewhat higher for the UC group at each visit, remained below 10% through six years for both groups. Participants who were randomized early in the recruitment period came to the clinic for annual visits beyond the sixth; however, data on risk factor change is presented in this report only through the sixth, the last visit that the entire surviving cohort could have attended.

Risk Factor Reduction

A necessary intermediate goal of

e trial was to obtain adequate luctions, through intervention, of e three major modifiable CHD risk tors (Fig 1). For each of these, ly statistically significant <.01) differences between the SI d UC groups were observed at each nual visit.

The mean diastolic BP at the first reening visit, S_1, for men subsequently randomized was 99.2 mm Hg. seline diastolic pressure, defined as e average of S_2 and S_3 random-zero adings, was 91.0 mm Hg, with gression to the mean probably counting for much of the decrease om S_1. By 12 months, average reductions from baseline of 6.3 mm Hg for men and 2.5 mm Hg for UC men re observed (Table 2). By 72 nths, these reductions were 10.5 n Hg and 7.3 mm Hg, respectively. the men randomized, 19% reported baseline being prescribed antihytensive medication; at six years, 7 of SI men and 47% of UC men ported such prescription. Of SI men ated for hypertension, 58% had stolic pressures lower than 90 mm at six years. The average percent luction from baseline to 72 months ng all SI men with S_1 diastolic asure of 95 mm Hg or higher was %, a figure exceeding design expections; however, the corresponding luction for UC men (unanticipated the design) was 8%. The SI-UC ference in diastolic BP averaged r annual visits was 4%, approxitely 75% of the design goal used sample size calculations. Among e 22 clinical centers, differences in an diastolic BP at 72 months for SI d UC participants ranged from 0.2 5.1 mm Hg.

At the time of randomization, 59% all men reported themselves as rent cigarette smokers (Table 2). r men who reported smoking at S_1, ted quit rates at 12 months were % for SI men and 14% for UC men; 72 months, these were 50% and . Thiocyanate-adjusted quit rates 12 months were 31% for SI men d 12% for UC; at 72 months, these re 46% and 29%, respectively. The ported and the thiocyanate-adted SI-UC differences, stated in ms of mean change in number of ettes smoked per day for all rticipants, exceeded design goals by % and 45%, respectively. At 72 nths, the SI-UC differences in

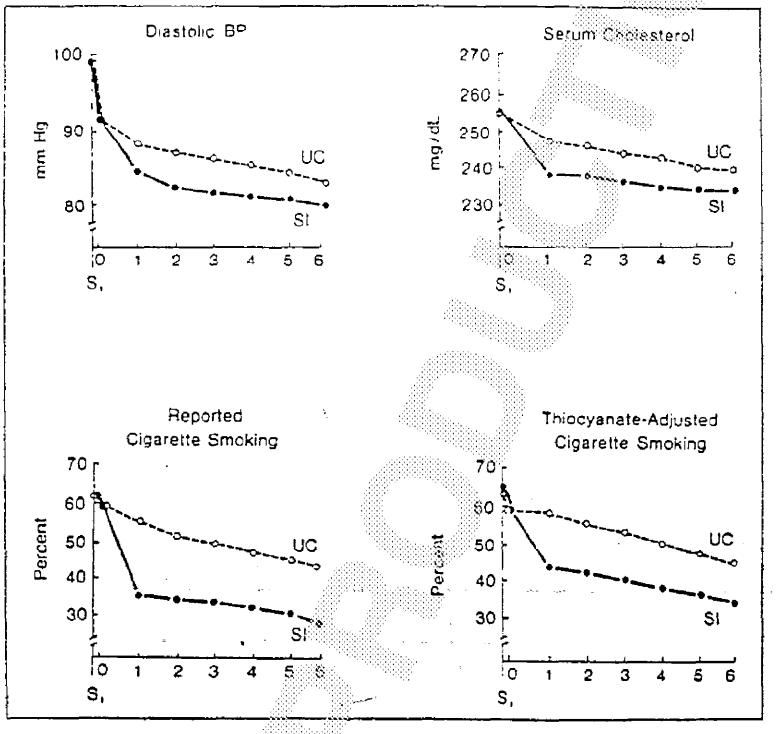

Fig 1.—Mean risk factor levels by year of follow-up for Multiple Risk Factor Intervention Trial Research Group participants. SI indicates special intervention; UC, usual care; S_1, first screening visit.

Table 2.—Mean Risk Factor Levels at Screening and Annual Visits for MRFIT SI and UC Men*

	Screening		Annual Visits, mo					
	S_1	S_2/S_3	12	24	36	48	60	72
			Diastolic BP, mm Hg†					
SI	99.2	91.0‡	84.7	82.5	82.0	81.6	81.2	80.5
UC	99.2	90.8‡	88.4	86.9	86.3	85.6	84.8	83.8
			Reported Cigarette Smoking, %					
SI	63.8	59.3	35.9	35.2	35.1	33.9	32.6	32.3
UC	63.3	59.0	55.6	52.2	50.5	48.2	46.7	45.6
			Serum Cholesterol, mg/dL§					
SI	250.8	...	238.4	238.2	236.9	235.4	234.9	235.5
UC	253.5	...	248.8	246.0	244.2	243.4	240.6	240.3
			Plasma Cholesterol, mg/dL§					
SI	...	240.3	...	229.9	228.1	227.2	226.6	228.2
UC	...	240.6	...	237.2	235.1	234.7	232.3	233.1
			Plasma LDL Cholesterol, mg/dL					
SI	...	159.8	...	150.7	...	148.1	...	148.7
UC	...	160.3	...	157.3	...	154.5	...	152.9
			Plasma HDL Cholesterol, mg/dL					
SI	...	42.0	...	42.8	...	42.8	...	41.7
UC	...	42.1	...	43.3	...	43.0	...	41.9
			No. of Participants at Each Visit					
SI	6,428	6,428	6,112	5,095	5,883	5,791	5,682	6,754
UC	6,438	6,438	6,080	5,919	5,793	5,711	5,615	5,639

*MRFIT indicates Multiple Risk Factor Intervention Trial Research Group; SI, special intervention; UC, usual care; LDL, low-density lipoprotein; HDL, high-density lipoprotein.

†All readings except S_1 are by the random-zero manometer.

‡The average of S_2 and S_3 BP readings is defined as baseline and given here.

§Both serum and plasma cholesterol level determinations were made, the latter were consistently lower as reported by others.[1]

Table 3.—Number of Deaths and Cumulative Mortality (per 1,000) by Year of Follow-up for MRFIT SI and UC Men*

	No. of Deaths						Cumulative Mortality, Deaths per 1,000 Men					
	CHD		CVD		All Causes		CHD		CVD		All Causes	
Year	SI	UC	SI	UC	SI	UC	SI	UC	SI	UC	SI	UC
1	11	9	14	10	19	17	1.7	1.4	2.2	1.6	3.0	2.6
2	11	20	14	23	22	31	3.4	4.5	4.4	5.1	6.4	7.5
3	16	18	17	20	29	37	5.9	7.3	7.0	8.2	10.9	13.2
4	16	16	18	18	34	39	8.4	9.8	9.8	11.1	16.2	19.3
5	21	15	25	19	52	41	11.7	12.2	13.8	14.0	24.3	25.6
6	17	26	24	33	55	54	14.4	16.3	17.5	19.2	32.8	34.0
6-yr Total†	92	104	112	123	211	219	...	...	...	...	...	...
As of 2/28/82‡	115	124	138	145	265	260	17.9	19.3	21.5	22.5	41.2	40.4

*MRFIT indicates Multiple Risk Factor Intervention Trial Research Group; SI, special intervention; UC, usual care; CHD, coronary heart disease; CVD, cardiovascular disease.

†All men had at least six years of follow-up.

‡Mortality rates as of Feb 28, 1982, the last day of follow-up for all men, are simple proportions; for years 1 through 6, life table rates are given.

Table 4.—Frequency Distribution of Deaths by Cause for MRFIT SI and UC Men*

	Special Intervention		Usual Care	
Cause of Death	n	% of Total	n	% of Total
Coronary heart disease (CHD)	115	43.4	124	47.7
Myocardial infarction (MI)†	38	14.3	35	13.5
Sudden death (without documented MI)				
Within 60 min of being seen alive	54	20.4	56	21.5
Within 24 hr, but more than 60 min of being seen alive	18	6.8	25	9.6
Congestive heart failure due to CHD‡	1	0.4	4	1.5
Coronary surgery death§	4	1.5	4	1.5
Other cardiovascular disease	23	8.7	21	8.1
Stroke	13	4.9	11	4.2
Hypertension with left ventricular failure	0	0.0	1	0.4
Pulmonary embolus	3	1.1	3	1.2
Other	7	2.6	6	2.3
Noncardiovascular disease	116	43.8	109	41.9
Neoplasia	81	30.6	69	26.5
Lung	34	...	28	...
Colorectal	8	...	6	...
Other GI	20	...	11	...
Other	19	...	24	...
Liver disease	4	1.5	4	1.5
Lung disease	2	0.8	2	0.8
Suicide	7	2.6	8	3.1
Homicide	5	1.9	5	1.9
Accident	10	3.8	14	5.4
Other	7	2.6	7	2.7
Unknown cause of death	11	4.2	6	2.3
Total	265	100.0	260	100.0

*MRFIT indicates Multiple Risk Factor Intervention Trial Research Group; SI, special intervention; UC, usual care; GI, gastrointestinal tract.

†Myocardial infarction, documented by clinical or autopsy evidence, with death occurring within 30 days of onset of symptoms or during hospitalization for acute MI.

‡Without documented MI.

§Death from hospitalization for surgery for coronary heart disease or from complications of such an operation.

thiocyanate-adjusted quit rates for the 22 centers ranged from 6% to 24%.

Mean plasma cholesterol level at S_1 (relatively free of regression to the mean because, unlike the cholesterol level at S_1, it was not used as an eligibility criterion to select men at high risk) was 240 mg/dL. After two years there were reductions of 10.4 mg/dL for SI men and 3.4 mg/dL for UC men; after six years the mean levels were 12.1 mg/dL and 7.5 mg/dL below baseline for SI and UC men, respectively. These reductions, which primarily represent changes in low-density lipoprotein (LDL)-cholesterol and not high-density lipoprotein (HDL)-cholesterol (Table 2), amount to an SI-UC difference in total cholesterol of 4.6 mg/dL, or 2%. With the less-than-anticipated reduction among SI men and the unexpected decline among UC men, the SI-UC difference was about 50% of goal. Differences among the 22 centers in mean plasma cholesterol levels varied from −1.6 to 10.4 mg/dL at 72 months.

Several approaches were used to estimate the combined risk factor reductions. Incorporating the observed changes for the three risk factors into an expression for the relative odds (SI/UC) of CHD death using a Framingham risk function yielded an estimated relative odds 30% short of goal at 12 months, 10% short at 48 months, and nominally at goal at 72 months. This convergence to design goal largely reflects the design prediction of larger initial differentials followed by increasingly poor adherence, whereas the data show long-term maintenance of more modest initial differences. An analysis based on averaging calculated CHD risks for each participant over the six years of follow-up, indicated a potential net CHD mortality lowering of 22.2% rather than the 26.6% considered possible at the design stage; thus, this computation implies achievement of 83% of the SI-UC risk factor difference initially assumed in the design.

Mortality, All SI and UC Participants

As of Feb 28, 1982, after an average period of follow-up of seven years, there were 260 deaths among UC men, of which 124 were ascribed to CHD and 145 to cardiovascular causes (including CHD). Of 265 SI deaths, 115 were ascribed to CHD and 138 to CVD (Tables 3 and 4). The key mortality endpoints of CHD and CVD were 7.1% and 4.7% less, respectively, in the SI compared with the UC group, while the death rate for all causes was 2.1% higher for the SI men. The corresponding life table (log rank) Z values for the endpoints are

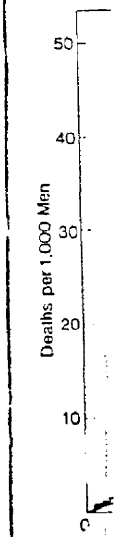

Fig 2.- (CHD) Risk part ing usu special with UC

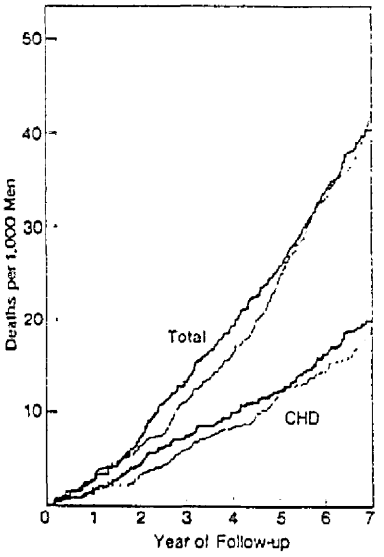

Fig 2.—Cumulative coronary heart disease (CHD) and total mortality rates for Multiple Risk Factor Intervention Trial Research Group participants. Heavy line indicates men receiving usual care (UC); thin line, men receiving special intervention (SI). Number of men alive with follow-up of seven years or longer: 3,117 UC and 3,118 SI.

Table 5.—Number of CHD and Total Deaths and Mortality Rate (per 1,000) by Baseline Risk Factor Levels*

	No. of Participants		CHD Deaths		Total Deaths	
	SI	UC	SI	UC	SI	UC
Nonhypertensive†						
Nonsmokers at S_1, Serum cholesterol						
<250 mg/dL	102	128	1(9.8)	1(7.8)	3(29.4)	2(15.6)
≥250 mg/dL	415	432	3(7.2)	4(9.3)	5(12.0)	6(13.9)
Smokers at S_1, Serum cholesterol						
<250 mg/dL	848	844	16(18.9)	11(13.0)	36(42.6)	30(35.5)
≥250 mg/dL	1,046	1,041	15(14.3)	29(27.9)	47(44.9)	53(50.9)
Hypertensive‡						
Nonsmokers at S_1, Serum cholesterol						
<250 mg/dL	620	627	2(3.2)	11(17.5)	14(22.6)	25(39.9)
≥250 mg/dL	1,188	1,160	23(19.4)	19(16.4)	42(35.4)	37(31.9)
Smokers at S_1, Serum cholesterol						
<250 mg/dL	1,388	1,369	30(21.6)	28(20.5)	68(49.0)	66(48.2)
≥250 mg/dL	823	837	25(30.4)	21(25.1)	50(60.8)	41(49.0)
Subtotals						
Nonhypertensive	2,409	2,445	35(14.5)	45(18.4)	91(37.8)	91(37.2)
Hypertensive	4,019	3,993	80(19.9)	79(19.8)	174(43.3)	169(42.3)
Serum cholesterol						
<250 mg/dL	2,958	2,968	49(16.8)	51(17.2)	121(40.9)	123(41.4)
≥250 mg/dL	3,470	3,470	66(19.0)	73(21.0)	144(41.5)	137(39.5)
Nonsmokers at S_1	2,325	2,347	29(12.5)	35(14.9)	64(27.5)	70(29.8)
Smokers at S_1	4,103	4,091	86(21.0)	89(21.8)	201(49.0)	190(46.4)
Total	6,428	6,438	115(17.9)	124(19.3)	265(41.2)	260(40.4)

*For Multiple Risk Factor Intervention Trial Research Group participants. SI indicates special intervention; UC, usual care; CHD, coronary heart disease.
†Baseline diastolic BP (average of two R-Z readings at S_1 and S_2) less than 90 mm Hg and not receiving antihypertensive treatment at S_1.
‡Baseline diastolic BP ≥90 mm Hg or receiving antihypertensive treatment at S_1.

Table 6.—Number of CHD and Total Deaths and Mortality Rate (per 1,000) by Hypertensive Status at Baseline*

	No. of Participants		CHD Deaths		Total Deaths	
	SI	UC	SI	UC	SI	UC
Nonhypertensive†	2,409	2,445	35(14.5)	45(18.4)	91(37.8)	91(37.2)
Hypertensive‡	4,019	3,993	80(19.9)	79(19.8)	174(43.3)	169(42.3)
Receiving treatment at S_1	1,261	1,227	28(22.2)	26(21.2)	59(46.8)	54(44.0)
Not receiving treatment at S_1, mm Hg						
90-94§	1,157	1,181	17(14.7)	12(10.2)	47(40.6)	31(26.2)
95-99§	830	848	19(22.9)	19(22.5)	43(51.8)	39(46.1)
≥100§	771	739	16(20.8)	22(29.8)	25(32.4)	45(60.9)
Total	6,428	6,438	115(17.9)	124(19.3)	265(41.2)	260(40.4)

*For Multiple Risk Factor Intervention Trial Research Group participants. SI indicates special intervention; UC, usual care; CHD, coronary heart disease.
†Baseline diastolic BP (average of two R-Z readings at S_1 and S_2) less than 90 mm Hg and not receiving antihypertensive treatment at S_1.
‡Baseline diastolic BP ≥90 mm Hg or receiving antihypertensive treatment at S_1.
§Baseline diastolic BP

+0.6, +0.4, and −0.2. None of these is statistically significant. A slight mortality advantage of the SI group, as shown by the separation of the cumulative mortality curves beginning at about two years, waned by year 5 (Fig 2). Of the 22 clinical centers, 11 had more CHD deaths among UC men than among SI; for total mortality, ten centers had more UC than SI deaths.

The number of deaths from noncardiovascular causes was also similar in the two groups (116 SI *v* 109 UC). There were 81 cancer deaths in the SI group and 69 in the UC, resulting from lung cancer (34 SI *v* 28 UC), colorectal cancer (8 SI *v* 6 UC), other gastrointestinal neoplasms (20 SI *v* 11 UC), and other neoplasia (19 SI *v* 24 UC).

The number of deaths in the UC group was substantially short of expectation for the six complete years of follow-up as well as for the average follow-up period of seven years. Based on design risk factor change assumptions and Framingham risk functions, 442 deaths (including 187 from CHD) were expected by the end of six years of follow-up among the 6,438 UC men; only 219 (including 104 from CHD) occurred. By the end of follow-up for all men, the total of 260 UC deaths (including 124 from CHD) was still well below the number expected for the six-year follow-up period. The approximate 90% CI for the percentage change in CHD mortality attributable to MRFIT intervention is therefore large, ranging from a 25% decrease to a 15% increase.

Mortality in Baseline-Defined Subgroups

Comparisons of mortality rates for SI and UC men within subgroups defined by prerandomization characteristics preserve the comparability provided by the randomization but

Table 7.—Number of CHD and Total Deaths and Mortality Rate (per 1,000) by Hypertensive Status at Baseline and by Presence of Resting ECG Abnormalities*

	No. of Participants		CHD Deaths		Total Deaths	
	SI	UC	SI	UC	SI	UC
Nonhypertensive						
Resting ECG abnormalities†						
Absent	1,817	1,862	24 (13.2)	30 (16.1)	71 (39.1)	63 (33.8)
Present	592	583	11 (18.6)	15 (25.7)	20 (33.8)	28 (48.0)
Total	2,409	2,445	35 (14.5)	45 (18.4)	91 (37.8)	91 (37.2)
Hypertensive						
Resting ECG abnormalities†						
Absent	2,785	2,808	44 (15.8)	58 (20.7)	100 (35.9)	122 (43.4)
Present	1,233	1,185	36 (29.2)	21 (17.7)	74 (60.0)	47 (39.7)
Total	4,018	3,993	80 (19.9)	79 (19.8)	174 (43.3)	169 (42.3)

*For Multiple Risk Factor Intervention Trial Research Group participants. SI indicates special intervention; UC, usual care; MC, Minnesota Code.

†Abnormalities include high R waves in the precordial leads (MC, 3.1;3.3;3.4; N=1,410), negative T waves (MC, 5.1-5.3; N=511); R-R′ pattern (MC, 7.5; N=488); ectopic ventricular premature beats (MC, 8.1; N=452); left axis deviation ≤−30°. (N=380); incomplete RBBB (MC, 7.3; N=359); ST depression (MC, 4.1-4.3; N=237); ST elevation (MC, 9.2; N=240); major Q waves (MC, 1.1-1.3; N=184); short P-R (MC, 6.5, N=109); first degree atrioventricular block (MC, 6.3; N=66); supraventricular tachycardia (MC, 8.4; N=38); right axis deviation ≥+120° (N=17); and other rare conditions (N=36).**

Table 8.—Number of CHD and Total Deaths and Mortality Rate (per 1,000) by Baseline Risk Factor Levels for the Subgroup of MRFIT SI and UC Participants Without Resting ECG Abnormalities at Entry*

	No. of Participants		CHD Deaths		Total Deaths	
	SI	UC	SI	UC	SI	UC
Nonhypertensive†						
Nonsmokers at S_1						
Serum cholesterol						
<250 mg/dL	78	93	1 (12.8)	1 (10.8)	3 (38.5)	2 (21.5)
≥250 mg/dL	324	340	1 (3.1)	3 (8.8)	3 (9.3)	3 (8.8)
Smokers at S_1						
Serum cholesterol						
<250 mg/dL	618	635	11 (17.9)	8 (12.6)	28 (45.5)	21 (33.1)
≥250 mg/dL	799	794	11 (13.8)	18 (22.7)	37 (46.3)	37 (46.6)
Hypertensive†						
Nonsmokers at S_1						
Serum cholesterol						
<250 mg/dL	439	445	1 (2.3)	7 (15.7)	9 (20.5)	17 (38.2)
≥250 mg/dL	851	852	13 (15.3)	15 (17.6)	23 (27.0)	27 (31.7)
Smokers at S_1						
Serum cholesterol						
<250 mg/dL	928	922	21 (22.6)	21 (22.8)	46 (49.5)	49 (53.1)
≥250 mg/dL	567	589	9 (15.9)	15 (25.5)	23 (40.6)	29 (49.2)
Subtotals						
Nonhypertensive	1,817	1,862	24 (13.2)	30 (16.1)	71 (39.1)	63 (33.8)
Hypertensive	2,785	2,808	44 (15.8)	58 (20.7)	100 (35.9)	122 (43.4)
Serum cholesterol						
<250 mg/dL	2,061	2,095	34 (16.5)	37 (17.7)	85 (41.2)	89 (42.5)
≥250 mg/dL	2,541	2,575	34 (13.4)	51 (19.8)	86 (33.8)	96 (37.3)
Nonsmokers at S_1	1,692	1,730	16 (9.5)	26 (15.0)	38 (22.5)	49 (28.3)
Smokers at S_1	2,910	2,940	52 (17.9)	62 (21.1)	133 (45.7)	136 (46.3)
Total	4,602	4,670	68 (14.8)	88 (18.8)	171 (37.2)	185 (39.6)

*MRFIT indicates Multiple Risk Factor Intervention Trial Research Group; SI, special intervention; UC, usual care; CHD, coronary heart disease.

†Baseline diastolic BP (average of two R-2 readings at S_1 and S_2) less than 90 mm Hg and not receiving antihypertensive treatment at S_1.

‡Baseline diastolic BP ≥90 mm Hg or receiving antihypertensive treatment at S_1.

have less precision as a result of the reduced sizes of the groups. There is also the increased likelihood of overinterpreting nominally significant differences resulting from the examination of multiple comparisons, some of which were defined post hoc. However, the subgroup findings need exploration, especially to provide insight into the overall result and to indicate areas for further investigation.

The relationship of mortality to baseline levels of the three risk factors is shown in Table 5, where numbers of deaths by cause together with corresponding mortality rates are given for SI and UC men. The mortality rates for smokers, for hypercholesterolemic (≥250 mg/dL) and for hypertensive men are given as subtotals in the lower rows. For each of these three groups, the mortality rates are similar for SI and UC men. However, it must be remembered that subgroups defined by the presence or absence of one of the three major risk factors are not otherwise comparable; for example, because of the selection procedure used, nonsmokers have on the average higher blood cholesterol and BP levels than smokers. Despite this complexity, it may be noted in the subtotals that CHD mortality, and in most cases total mortality, tends to be higher in smokers, in participants with hypercholesterolemia, and in those with hypertension, supporting the risk factor status of these variables within this cohort.

Among the group of all nonhypertensive men at baseline, there was a 21% lower CHD death rate (CI, −22% to 50%) for the SI group compared with UC men, but no comparable difference in deaths from all causes. Of the four substrata of men not hypertensive at baseline, the largest, consisting of cigarette smokers who were hypercholesterolemic, is of particular interest for its resemblance to the group of men in the Oslo primary prevention trial that recently reported positive findings (see Comment). The CHD mortality rate is 49% lower (CI, 8% to 75%) for the SI group compared with the UC group (15 SI deaths *v* 29 UC deaths), with a smaller difference observed for total mortality. Given the presence of both cigarette smoking and hypercholesterolemia, BP levels of men in this substratum of those not hypertensive at baseline were lower than those for the other three substrata, as a result of the risk-selection criteria; consequently, a relatively small percentage of the SI men in this substratum subsequently became hypertensive and received antihypertensive treatment.

Of the four substrata of hypertensive men, only in the smallest, consisting of nonsmokers who were not

hypercholesterolemic, was the CHD rate lower for SI men. With only one of the three risk factors present, this group, to meet the MRFIT risk-eligibility criteria, was necessarily made up of men with more severe degrees of hypertension.

A more detailed breakdown by hypertensive status at entry is given in Table 6. Among hypertensive men not receiving treatment at entry, the differences in SI and UC CHD and total mortality rates differ by level of baseline diastolic BP. The percentage differences in CHD mortality rates are −45% (17 SI CHD deaths *v* 12 UC), −2% (19 SI CHD deaths *v* 19 UC), and +30% (16 SI CHD deaths *v* 22 UC), respectively, for participants with baseline diastolic BP levels of 90 to 94, 95 to 99, and 100 mm Hg or higher. The corresponding differences for total mortality are −55% (47 SI deaths *v* 31 UC), −12% (43 SI deaths *v* 39 UC), and +47% (25 SI deaths *v* 45 UC).

Analyses related to one of the formal subgroup hypotheses (see Methods) suggested a possible explanation for the results observed in hypertensive men. Abnormalities on the baseline resting ECG seemed to be associated with an excess of CHD mortality in the SI compared with the UC group, with the effect limited to hypertensive persons (Table 7). For the group of hypertensive men without ECG abnormalities, a 24% lower death rate was noted in the SI group (44 SI CHD deaths *v* 58 UC). This difference is similar to the 21% found for normotensive men with or without ECG abnormalities (35 SI CHD deaths *v* 45 UC). For the group of hypertensive men with ECG abnormalities, there were 15 more SI deaths than UC (36 SI CHD deaths *v* 21 UC). This percentage difference (−65%) is larger than, and in the opposite direction from, the corresponding difference for hypertensive men without ECG abnormalities. Similar findings, though not as pronounced, are found for total mortality (Table 7).

With this possibility that participants with abnormal ECG at baseline responded adversely to MRFIT intervention, the mortality results are retabulated by baseline risk factors for the 72% of men with a normal baseline resting ECG (Table 8). Such analyses are complicated because of the previously mentioned reciprocal and overlapping relationships of risk factor levels among the participants. For each subgroup listed in the lower half of Table 8, the SI men experienced fewer CHD deaths than did the corresponding UC group. A comparison of the results in Table 8 for men without ECG abnormalities at baseline with those for the total cohort in Table 5 reveals that for nearly all risk factor combinations there were fewer SI CHD deaths than UC for this large subgroup. There is a difference in CHD mortality of 24% (CI, −13% to 49%) for hypertensives without ECG abnormalities, and a 32% difference (CI, −3% to 57%) for those with cholesterol levels of 250 mg/dL or higher and without ECG abnormalities. The lower CHD mortality for SI compared with UC men in these subgroups, consisting of a large majority of the total MRFIT cohort, is similar to the mortality reduction expected based on the design of the trial.

Table 9.—Number of CHD and Total Deaths and Mortality Rate (per 1,000) for Smokers at Entry S, by Smoking Status at 12 Months and Amount Smoked at Entry*

	No. of Participants		CHD Deaths		Total Deaths	
	Quit†	Did Not Quit	Quit†	Did Not Quit	Quit†	Did Not Quit
Special intervention						
1-29 cigarettes/day Reported at S,	454	806	6(13.2)	19(23.6)	13(28.6)	34(42.2)
≥30 cigarettes/day Reported at S,	537	2,036	5(9.3)	39(19.2)	16(29.8)	99(48.6)
Usual care						
1-29 cigarettes/day Reported at S,	159	1,021	3(18.9)	23(22.5)	8(50.3)	44(43.1)
≥30 cigarettes/day Reported at S,	215	2,435	1(4.7)	47(19.3)	7(32.6)	101(41.5)

*For Multiple Risk Factor Intervention Trial Research Group participants. CHD indicates coronary heart disease. Deaths during the first year of follow-up are excluded.

†Quitters are S, smokers who reported quitting at 12 months with serum thiocyanate levels (at 12 months) lower than 100 μmole/L.

Mortality in Subgroups Defined After Randomization

Since the smoking intervention was the most successful relative to the risk factor design goals, yet the CHD mortality differences between SI and UC men who had been smokers at baseline were modest (Tables 5 and 8), the relationship between smoking cessation and mortality was examined further. In men who quit smoking during the first year, subsequent death rates were compared with the rates in those who continued to smoke, controlling for the reported number of cigarettes per day at baseline (Table 9). It must be emphasized that this kind of analysis does not preserve the randomized controlled design of the MRFIT, and must be interpreted with regard for the possibility of confounding by many factors. In both the SI and the UC groups, those who quit smoking had significantly lower rates of CHD and, for the most part, total mortality. Multivariate analyses controlling for critical variables, including the other major risk factors, have consistently supported the relationship between smoking cessation and CHD mortality.

COMMENT

Strengths and Limitations of the Data

This large and complex trial was operationally successful. The recruitment phase was completed in a 28-month period and, in numbers recruited, exceeded the design goal. Randomization proceeded without incident, the two randomized groups being well balanced on numerous relevant characteristics. The completeness of follow-up exceeded expectations, with 91% of those alive returning for the sixth annual visit. For mortality endpoints, requirements of thorough documentation of all deaths and "blinded" classification of causes of death were met.

Intervention accomplishments in the SI group, which have been reported in detail,[1] were substantial: smoking cessation was much more successful than had been expected, the BP reduction in the SI group exceeded the desired drop in diastolic BP, and the effect on cholesterol lowering was considerable but less

than had been sought. A notable achievement of the intervention program was a continued decline in mean risk factor levels after the substantial drop in the first year.

Risk factor changes were also observed in the UC group, though to a lesser degree. Whereas it had been projected on the basis of the best information available ten years ago that this group would exhibit over six years no important changes in BP and serum cholesterol levels, and only minimal change in smoking habits, the actual findings were very different. Sizable reductions occurred in the levels of all three risk factors for UC men. Thus, over six years, reported cigarette smoking declined from 59% to 46%, the diastolic BP from a baseline value of 90.9 to 83.6 mm Hg, and plasma cholesterol levels from 241 to 233 mg/dL. Also, 47% of the UC men were receiving antihypertensive medication at the end of the sixth year compared with 19% at baseline.

The cause of these unanticipated changes in the UC group is speculative. Contributing elements to the risk factor reductions may include the psychological impact on the UC men of enrollment in a trial limited to persons at high risk of heart attacks, the possibility that persons volunteering for a six-year trial are unusually health conscious and motivated to change, sensitization of the UC men to their risk factor status resulting from annual visits to the clinical centers, and the broad influence of health education in the United States aimed at modifying all of the three risk factors. The physicians of the UC men may well have instituted their own preventive programs. Ethical considerations prompted notification of these physicians of the findings from each annual visit, although the MRFIT centers made no recommendation regarding intervention for UC men.

The risk factor changes in the UC group may be relevant to one of the assumptions on which the power of the trial was based and that has been shown to be inaccurate. The number of deaths in the UC group was substantially short of expectation. By the end of follow-up (an average of 7.0 years) for all men, the total of 260 UC deaths (including 124 from CHD) was still slightly less than two thirds the number expected for the six-year follow-up period.

Several factors may have contributed to the lower-than-expected UC mortality: (1) the recent reduction in CHD mortality in the United States, the reasons for which are still not totally understood"; (2) exclusion criteria applied to the MRFIT screened group that may have been more stringent than those applied to data from the Framingham cohort during the design phase of MRFIT, resulting in the selection of men with a lower than expected mortality in both the SI and UC groups; (3) the phenomenon of lower-than-expected mortality in almost all clinical trials involving human volunteers; and (4) finally, the substantial risk factor changes made by UC men, as mentioned previously. The latter possibility can be entertained only if one assumes that risk-factor modification is effective in reducing mortality in high-risk men aged 35 to 57 years, the question the trial was designed to test.

The lower-than-predicted mortality for the UC group has the important effect of lowering the power from .88 to .75 for detecting the 26.6% SI-UC difference in mortality specified in the design. Furthermore, if the risk model based on Framingham data were accurate in predicting potential risk reduction, the unexpected decreases in UC risk-factor levels would also affect the power unfavorably. The power, based on the observed UC mortality rate, for detecting the 22% difference in CHD mortality predicted by the risk factor difference actually achieved, is about 0.6.

Interpretation of Mortality Results

The finding of percentage differences of only +7%, +5%, and −2% for CHD, CVD, and all-cause mortality rates, respectively, deserves careful examination. At least three possible explanations for these results must be considered: (1) such an intervention program is without benefit in terms of substantial decreases in mortality; (2) the intervention program does affect CHD mortality, but the benefit was not observed in this study; or (3) one or more constituents in the intervention program may have had an unfavorable effect on survival in some subgroups offsetting beneficial effects of others.

The first possibility, of ineffectiveness on CHD, CVD, and total mortality of programs to reduce cigarette smoking, treat hypertension with drugs, and lower elevated serum cholesterol levels by diet, seems inconsistent with most published scientific data: clinical, pathological, animal experimental, and epidemiologic." The trial was of course initiated to test this question in high-risk middle-aged men. Only one controlled trial limited solely to testing the benefit of reduction in or cessation of cigarette smoking has been executed; its results were inconclusive, but showed a favorable trend for CHD mortality.[9] A large body of scientific data supports the conclusion that cigarette smokers who reduce the amount of smoking or give it up entirely have improved life expectancy.[2] It is not clear, however, how long it takes after modification of smoking—especially heavy smoking—for favorable alterations of mortality rates to occur, and it may take longer than the seven-year duration of this trial to be clearly demonstrated.[12] Somewhat contrary to the possibility of a delayed effect is the observation that CHD mortality within the SI group subsequent to the first year of follow-up diverges sharply depending on smoking status at the 12-month visit. The rate in quitters who had smoked at least 30 cigarettes per day is approximately half that of those who continue smoking. Such within-group analyses, however, do not make use of the randomized control design of a clinical trial, and the results, while suggestive, leave open the possibility of confounding by other factors.

Regarding hypertension, a beneficial impact of drug treatment by a "stepped-care" protocol, as contrasted with "referred care," on total mortality has been described in a population of 10,940 men and women by the Hypertension Detection and Follow-up Program (HDFP).[13] For persons in the age group 30 to 49 years at entry, the difference in total mortality was 5.7%; for persons aged 50 to 59 years it was 25.3%.[14] The Australian National Blood Pressure Study, a placebo-controlled primary prevention trial in 3,427 men and women with mild hypertension, reported significantly fewer morbid and fatal events, including significantly fewer deaths from cardiovascular disease, in persons aged 30 to 69 years

who were treated with antihypertensive medication, but the corresponding percentage difference for all endpoints in the subgroup of men aged 30–49 years, though similar in magnitude, lacked statistical significance.[35] The earlier classic report from the Veterans Administration Cooperative Study concluded that treatment was effective in preventing congestive heart failure and stroke, but no statistically significant benefit for CHD mortality (six in the treated group, 11 in the placebo group) was found.[36]

In the area of lipid-lowering diet, some controversy has existed for years as to precise benefits, although most scientific including public health groups have concluded that benefits do indeed exist."[37] For example, the Los Angeles Veterans Administration Study, in a population of 846 institutionalized men aged 55 years and older, demonstrated significant reduction in mortality from atherosclerotic diseases, but not in total mortality.[38] The recently concluded Oslo trial in 1,232 high-risk nonhypertensive men aged 40 to 49 years combining lipid-lowering dietary intervention with smoking cessation showed statistically significant reductions in sudden coronary death and in CHD incidence, and substantial, though nonsignificant, reductions in CHD and total mortality. In the Oslo study, differential quit rates for cigarette smoking were less than those achieved in the MRFIT, but serum cholesterol differences were appreciably greater.[11] An overall impression from this partial review, particularly of recent clinical trials, is that the interventions used in the MRFIT would be expected to have a beneficial effect. However, sufficient differences from MRFIT exist in study design and related factors that firm conclusions are not possible.

The second possible explanation for the nonsignificant mortality outcome in the MRFIT is that the hypothesis received a less than definitive test, and the observed differences in mortality represent chance deviations from a larger effect that this intervention program has in the population. We have noted earlier that the power of the trial was lower than projected. One way to consider this problem, now that the trial has been completed, is through the 90% CI for CHD mortality. This ranged from a favorable effect of 25% to a harmful effect of 15%, an interval that includes the 22% benefit projected from the observed risk factor changes. A related approach is to compute the probability of observing a CHD mortality rate differential of 7.1% or less, given the observed mortality rate in the UC (19.3 deaths per 1,000) and the mortality reduction projected from the observed risk factor reduction (22%). This probability is .12, indicating that the observed result is not inconsistent with a hypothesized 22% mortality differential; however, it suggests that an effect of this magnitude is unlikely.

The third possible explanation, that some aspect of the intervention program has a deleterious effect on mortality in some subgroups, has been extensively investigated. Thus, we observed that the men who stopped smoking cigarettes were considerably less successful in weight control than were men who continued to smoke,[5] yet against any important negative influence was the finding that weight reduction was greater, overall, for SI than UC men.[7] Also, diuretics seem to increase the level of plasma cholesterol, and men who took such drugs (including nearly all hypertensive men in the SI group) had a blunting of the dietary hypocholesterolemic effect such that they achieved only about half of the cholesterol-lowering seen in men not receiving these drugs and a modest elevation of plasma triglyceride levels.[7] While it might be reasonable to conclude that a lessened lipid-lowering might mean a lessened improvement in CHD, CVD, and total mortality, one could hardly conclude that this effect actually increased mortality.

Another possibility, namely, that other aspects of drugs used in the treatment of hypertension in MRFIT contributed to an increased mortality, was explored. It was noted that among those hypertensive at baseline (and therefore most likely to have antihypertensive drug therapy), intervention did not result in an appreciable difference in number of deaths from CHD in the two groups (80 SI deaths and 79 UC deaths). When examined further, it seemed that the largest percentage increase in CHD mortality for SI compared with UC occurred in men with hypertension at entry whose baseline resting ECGs showed signs of abnormalities. These findings are not conclusive, but the possibility that the use of pharmacologic therapy in these subgroups is associated with an increased CHD mortality warrants further investigation.

In some contrast with the ambiguous but disquieting results in those with hypertension are the findings in other subgroups. Here again, we mention that such subgroup data are cited with awareness of their limitations and to indicate trends and avenues for future study. Among those not hypertensive at baseline, but of course possessing other risk factors, there were 35 deaths from CHD in the SI men and 45 deaths in the UC group. Furthermore, examination of the mortality data for men with serum cholesterol values of 250 mg/dL or more at the first screening visit, but without hypertension, revealed 18 deaths from CHD in the SI group and 33 in the UC group. Similarly, among those who were cigarette smokers at baseline but were not hypertensive, there were 31 coronary deaths in the SI category and 40 among the UC men. There is therefore a pattern, at least for CHD mortality, suggesting that among those MRFIT men free of hypertension at baseline, life-style changes may result in favorable reductions in mortality.

Thus, of the possible interpretations of the mortality results, the last discussed—a combination of favorable and unfavorable effects of the intervention program—seems most plausible. Even with the unexpected sizable risk factor reduction among the UC men, the lower-than-expected UC mortality, and the duration of intervention averaging only seven years, the likelihood that these factors resulted in missing an overall positive effect is relatively low. The data suggest that, except for some groups of hypertensive persons, particularly those with resting ECG abnormalities, the MRFIT intervention is apparently associated with a lower CHD mortality in the SI group.

CONCLUSION

In conclusion, we have shown that it is possible to apply an intensive long-term intervention program against three coronary risk factors with considerable success in terms of

risk factor changes. The overall results do not show a beneficial effect on CHD or total mortality from this multifactor intervention. These results are accompanied by an apparent heterogeneity of effects among sizable subgroups, but there must be caution in reaching conclusions from such subgroup data. It may be relevant that multifactor intervention received a less than optimal test owing, in part, to unexpected declines in risk factor levels and, in part, to lower-than-expected mortality in the UC group. In regard to the former, the UC men thus constituted to a considerable extent a "treated" group.

The SI-UC comparisons indicate that among men with normal baseline ECGs, the MRFIT intervention program may have had a favorable effect on CHD mortality. The data also suggest that men with hypertension, primarily those with resting ECG abnormalities, had no favorable, and possibly an unfavorable response to intervention. More study is required to clarify this issue and its possible relation to antihypertensive treatment. Findings also include the within-group observation that men who stopped cigarette smoking had lower CHD and total mortality than those who continued to smoke.

The results of this trial do not address the possible effects of risk-factor intervention carried out over time periods of a decade or more or those begun before middle age. Future publications will address the morbidity results of the trial, subgroup hypotheses, and the role of other major variables.

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[redacted]

RESPONSE TO QUERY/
Q'S AND A'S

2025880332

PRIVILEGED: PREPARED FOR LEGAL COUNSEL

FOR RESPONSE TO INQUIRY ONLY

The message in question was a fair and accurate commentary providing R.J. Reynolds Tobacco Company's opinion on one aspect of a significant public controversy, the smoking and health issue. However, the key issue at stake in this proceeding by the Federal Trade Commission is the right of a company to comment on important public matters.

This proceeding by the FTC poses a serious threat to the freedom of speech of companies and individuals alike. Reynolds will take all appropriate steps to protect the right to express its opinion on matters of public controversy regardless of whether the views expressed are approved by the government and Reynolds expects to prevail.

###

QUESTIONS

1. What was the exact language of the ad?

A. Read message.

2. When did these ads begin?

A. This message was one of a series of public issues messages R.J. Reynold Tobacco began running in January 1984. The message in question first appeared in February 1985.

3. Is the ad still appearing? or, When is the ad scheduled to appear again?

A. This particular message last ran in June 1985. It is not scheduled to appear again.

4. Is Reynolds still running any of its public issues messages?

A. No. That portion of the program has been terminated.

5. Why?

A. There were a number of reasons. One reason was a desire to better focus the use of our limited resources.

6. Did the FTC investigations play any role in the decision to stop the Cigarettes and Science ad or the whole print campaign?

A. I think it is fair to say that the FTC's position that we did not have the right to express our view on matters of public concern and its misuse of its investigatory powers, which was evident from the beginning of our program, affected both decisions.

7. Any further questions on the company's First Amendment position?

A. We are being represented by Floyd Abrams -- who is, as you know, probably the leading First Amendment lawyer in the country. He will be glad to discuss First Amendment issues with you. His number is (212) 701-3621.

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[redacted]

SECTION 7 - TOBACCO INGREDIENTS/ADDITIVES RESPONSE TO QUERY

2025880336

2025880336

General Background
Tobacco Ingredients/Additives

On April 2, 1986, the nation's leading cigarette manufacturers, acting in compliance with the Federal Cigarette Labeling Act of 1984, provided the Department of Health and Human Services (HHS) with a list of flavorings, moisturizers and other ingredients added to tobacco in the production of cigarettes.

In total, added ingredients generally comprise no more than one percent of the tobacco weight of an individual cigarette, and no individual cigarette brand style would contain even a small fraction of the approximately 800 ingredients provided in the HHS list. Of the ingredients listed, about 30 such as cocoa, other sweetening ingredients and licorice account for about 80 percent of all ingredients added to tobacco as cigarettes are made.

None of the ingredients listed are used only in the manufacture of cigarettes. All can be found in a variety of other widely used consumer goods such as food products, toothpaste and mouthwash. Most of the ingredients listed have been commonly used in food products for decades and are contained on the GRAS (Generally Accepted as Safe) list maintained by the Flavor and Extract Manufacturers Association.

Most of the GRAS-list ingredients, and others on the overall list, have also been approved for use in cigarettes under guidelines issued by the Independent Scientific Committee on Smoking and Health that advises the Department of Health and Social Security of the United Kingdom, and by an agency of the West German government. In addition, the major U.S. cigarette manufacturers have carefully evaluated all ingredients used in their products either through their own testing or evaluation of available scientific studies.

The non-tobacco ingredients contained in the list are primarily flavoring materials, such as menthol, used to refine taste and enhance smoking quality to meet consumer desires. Others serve such functions as enhancing aroma or serving as moisturizers to help maintain product quality.

The blends of individual cigarettes are considered extremely important trade secrets by the tobacco industry in the same way the beverage industry considers the formulas for some soft drinks highly proprietary. Therefore, the list provided does not identify which tobacco companies use the individual ingredients listed. Because the blend information constitutes trade secrets, it is protected under the Federal Cigarette Labeling and Advertising Act.

The purpose in providing the ingredients list to HHS is to enable department scientists to test and assess such ingredients in their end use profile. The industry has stated that it stands ready to assist HHS scientists in their review of the list, and that it will cooperate by providing additional relevant information that may be useful to HHS as it conducts its evaluation.

A procedure for responding to query has been agreed to by the tobacco companies. Following this procedure, Covington & Burling would initially answer queries on behalf of the tobacco industry using the statement at the tab, "Statement for Covington & Burling in Response to Inquiries." Additional statements have been included as follows:

- Statement for Tobacco Companies to be used in Responding to Inquiries Concerning the Submission of Ingredient Information to HHS.
- Statement for the Tobacco Institute to be used in Responding to Inquiries Concerning the Submission of Ingredient Information to HHS.
- Draft Response of the Industry upon Disclosure of the Ingredients List.
- Questions and Answers Concerning Ingredients.

If queried on this matter, any response should be deferred and the questions referred to:

Mr. Stanley L. Temko
Covington & Burling
Telephone: (202) 662-5514

STATEMENT FOR
COVINGTON & BURLING
IN RESPONSE TO INQUIRIES

2025880340

2025880340

DRAFT - March 27, 1986

PRIVILEGED AND CONFIDENTIAL
ATTORNEYS' WORK PRODUCT

STATEMENT FOR
COVINGTON & BURLING
IN RESPONSE TO INQUIRIES

Covington & Burling, on behalf of the six major American cigarette manufacturers, submitted to the Department of Health and Human Services ("HHS") on April 2, 1986, an overall list of ingredients that are added to tobacco in the manufacture of cigarettes.

The submission was made in accordance with the requirements of the Federal Cigarette Labeling and Advertising Act and the HHS Federal Register announcement of December 3, 1985, implementing the requirements of the Act. Under the Act, companies which manufacture, package or import cigarettes into the United States must annually submit to HHS a list of ingredients added to tobacco in cigarette manufacture.

The Act provides that manufacturers required to provide a list may designate a third party to compile and submit a combined list of ingredients. Covington & Burling, in accordance with this provision, prepared and submitted a joint list on behalf of The American Tobacco Company, Brown & Williamson Tobacco Corporation, Liggett Group Inc., Lorillard, Inc., Philip Morris Incorporated, and R.J. Reynolds Tobacco Company.

The specific ingredients used by the companies are trade secrets and highly confidential proprietary information. Recognizing this, the Act specifically provides that the list of ingredients submitted to HHS need not identify the companies that use individual ingredients or the brands of cigarettes that contain particular ingredients. The Act further provides that HHS must adopt and follow procedures designed to protect the confidentiality of the list. These procedures were set forth in detail in the Federal Register announcement.

HHS will now be reviewing the list, and the cigarette manufacturers are prepared to discuss the list with the Department.

STATEMENT FOR TOBACCO COMPANIES CONCERNING THE SUBMISSION OF INGREDIENT INFORMATION TO HHS

2025880343

DRAFT - March 27, 1986

PRIVILEGED AND CONFIDENTIAL
ATTORNEYS' WORK PRODUCT

STATEMENT FOR TOBACCO COMPANIES TO BE USED IN RESPONDING TO INQUIRIES CONCERNING THE SUBMISSION OF INGREDIENT INFORMATION TO HHS

On April 2, 1986, the six major American cigarette manufacturers, including our company, provided the Department of Health & Human Services with a list of ingredients which are added to tobacco in the manufacture of cigarettes. This list was submitted to satisfy the requirements of Section 7(a) of the Federal Cigarette Labeling and Advertising Act, as amended.

The Act specifically provides that the list of ingredients submitted to HHS need not identify the companies that use individual ingredients or the brands of cigarettes that contain particular ingredients. The Act also directs HHS to treat the contents of the list as trade secret information, and HHS has adopted procedures to ensure the confidentiality of the list.

In view of the confidential status of the list, it would be inappropriate to comment on specific ingredients used in our products.

The six companies designated the Washington, D.C. law firm of Covington & Burling to compile the combined list which was submitted to HHS. Any questions concerning the ingredients submission should be directed to Stanley L. Temko of Covington & Burling (202-662-5514).

[redacted]

STATEMENT FOR TOBACCO INST.
CONCERNING THE SUBMISSION
OF INGREDIENT INFORMATION TO HHS

2025880345

2025880345

DRAFT - March 27, 1986

PRIVILEGED AND CONFIDENTIAL
ATTORNEYS' WORK PRODUCT

STATEMENT FOR THE TOBACCO INSTITUTE TO BE USED IN RESPONDING TO INQUIRIES CONCERNING THE SUBMISSION OF INGREDIENT INFORMATION TO HHS

Section 7(a) of the Federal Cigarette Labeling and Advertising Act, as amended, requires cigarette manufacturers to provide annually to the Department of Health & Human Services ("HHS") a list of ingredients that are added to tobacco in the manufacture of cigarettes. The Tobacco Institute has not been involved in any aspect of the preparation of submissions on behalf of any company. The six major American cigarette manufacturers have complied with the Act by submitting a list to HHS on April 2, 1986. Those six companies are The American Tobacco Company, Brown & Williamson Tobacco Corporation, Liggett Group Inc., Lorillard, Inc., Philip Morris Incorporated, and R.J. Reynolds Tobacco Company.

The companies have asked the Washington, D.C. law firm of Covington & Burling to compile the combined list which was submitted to HHS. Any questions concerning the ingredients submission should be directed to Stanley L. Temko of Covington & Burling (202-662-5514).

20258880347

2025880347

DRAFT - March 27, 1986

PRIVILEGED AND CONFIDENTIAL
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DRAFT RESPONSE OF THE INDUSTRY UPON DISCLOSURE OF THE INGREDIENTS LIST

A list of ingredients added to tobacco in the manufacture of cigarettes was recently disclosed by unknown sources and published in _____. The list had been provided to the Department of Health & Human Services (HHS) by the six major American cigarette companies in compliance with section 7 of the Federal Cigarette Labeling and Advertising Act.

The release of the list is unfortunate because the identities of the ingredients added to tobacco in cigarette manufacture are important trade secrets whose confidential status is recognized by the Act itself. We are disappointed that the list has been disclosed despite the confidentiality protection provided by law.

The Act envisions that HHS will conduct a scientific review of the ingredients on the list. The industry intends to participate in this review as it proceeds. Despite the unfortunate disclosure of the list, we hope that the issue of cigarette ingredients will continue to be approached from a scientific perspective.

Because of trade secret concerns, the ingredients used by particular companies or in specific brands cannot be

discussed. However, certain general comments will help place the contents of the list in perspective.

The list contains several hundred substances, many of which have been in use for decades. However, 15 substances account for approximately 99% of total ingredient usage. A number of these 15 compounds are processing aids that are found in the final cigarette in extremely small and often undetectable amounts. Others are casing materials, flavoring materials or moisturizers that have been used in cigarettes for decades.

The remaining ingredients are used in smaller quantities, in many cases less than 10 pounds per year for all the companies. Most of these compounds are components of formulated mixtures purchased by the cigarette manufacturers from flavor suppliers. Only a small quantity of flavor ingredients would be present in an individual brand, and all of these ingredients generally constitute less than a tenth of a percent by weight of an individual cigarette.

The submission of the list marks the second time in recent years that American cigarette manufacturers have made available an ingredients list to HHS. In 1982, representatives of the HHS Office of Smoking and Health reviewed a list of the most commonly used ingredients. This list was voluntarily provided by the industry under an agreement with Dr. Edward N. Brandt, Jr., then Assistant Secretary for Health at HHS. As in the past, the industry intends to participate in HHS' scientific review of the list.

Additional Comments Which Could Be Made By Covington & Burling Depending On The Type and Nature of Questions or Publicity

Most of the ingredients on the list are commonly used in foods, have been reviewed by the Food and Drug Administration (FDA), and are included in the lists of substances Generally Recognized as Safe maintained by FDA and the Flavor and Extract Manufacturers Association. Many ingredients are also used in other consumer products such as cosmetics.

Many of the ingredients on the list have also been approved for use in tobacco products by governmental bodies in other countries such as Great Britain and West Germany. For example, a British list, commonly referred to as the Hunter list, was developed by a medical and scientific committee appointed by the British government.

Q'S AND A'S RE: INGREDIENTS

2025880351

DRAFT - March 27, 1986

PRIVILEGED AND CONFIDENTIAL
ATTORNEYS' WORK PRODUCT

QUESTIONS AND ANSWERS CONCERNING INGREDIENTS

1. Why are ingredients used?

ANSWER: Some ingredients aid in processing tobacco in the initial stages of cigarette manufacture; these ingredients increase the efficiency and yield of processing operations but remain in the final cigarette in extremely small and often undetectable amounts. Other ingredients are used as casing materials or humectants. Casing materials help to smooth the taste of cigarettes, while humectants keep the tobacco in cigarettes moist. Finally, many of the ingredients are used to give individual brands of cigarettes their distinctive flavor and aroma.

2. How long have ingredients been used in cigarettes?

ANSWER: Ingredients have always been used in cigarettes. Most of the principal processing aids, casing materials, and humectants, for example, have not changed for decades. Many of the major flavoring agents have also been in use for an extensive period. Other flavors have been added or eliminated from time to time as new products have been

introduced or existing products have been reformulated in response to changing consumer preferences.

3. Why are so many ingredients used?

ANSWER: A relatively small number of ingredients, perhaps one-fourth of those on the list submitted to HHS, are separately added directly to tobacco during cigarette manufacture. Fifteen of those ingredients comprise over 99% of the total amount, by weight, of ingredients used in the industry. The other ingredients are used in smaller amounts, and most of the ingredients on the list submitted to HHS are used in extremely small quantities as part of flavor formulations purchased by the cigarette manufacturers. These formulations often include a number of ingredients, but typical industry-wide usage of most of these flavor components is under 10 pounds a year. The flavor formulations used by the companies change occasionally as new products are introduced or existing products are reformulated in response to consumer preferences.

4. Are ingredients used in large amounts?

ANSWER: Ingredients do not comprise a significant portion of the final cigarette. Certain ingredients which serve as processing aids are used in volume during the early stages of manufacturing but generally disappear

in the manufacturing process. The residual amounts of such processing aids in the final cigarette will be small and often undetectable. A small number of casing materials, moisturizers, and major flavors account for the great bulk of ingredients actually in cigarettes.

A larger number of the ingredients are used as flavors, but these substances are in the final cigarette in minuscule amounts. Most of the ingredients are constituents of proprietary flavor mixtures purchased from flavor suppliers, and usage of most of these ingredients by the entire industry is under 10 pounds per year. These ingredients will normally constitute less than one tenth of 1 percent by weight of the final product.

5. Haven't the cigarette manufacturers started using more and more ingredients to compensate for the reduction of tar and nicotine in cigarettes?

ANSWER: Most of the major ingredients used today have been used in cigarette manufacture for decades. It is true that, in recent years, a larger number of flavoring agents have been used -- in part because of an increased number of new brands and changes in existing brands. However, these flavoring ingredients are generally used in extremely small amounts and, in totality, represent less than one tenth of 1 percent by weight of the final cigarette.

6. Why hasn't the identity of ingredients been provided to the public before?

ANSWER: It is common for companies in highly competitive industries to guard specific product formulas. The flavoring agents added to foods and the fragrances included in cosmetics, for example, are treated as trade secrets and need not be disclosed on the labels of these products.

Because they contribute to the taste and appeal of individual brands, the identities of specific ingredients in cigarettes are also closely guarded trade secrets. Disclosure of the ingredients used in cigarette manufacture could reveal product formulas that required years of research to develop. The Federal Cigarette Labeling and Advertising Act recognizes the highly confidential nature of ingredients information by directing HHS to establish procedures to protect the confidentiality of the ingredients list.

Even though the ingredients are trade secrets, it should be noted that prior to the passage of Section 7(a) of the Federal Cigarette Labeling and Advertising Act in 1984, the industry had voluntarily cooperated with HHS on the question of ingredients. Under an agreement reached in 1982, the manufacturers had provided HHS with a list of commonly-used ingredients added to tobacco in the manufacture of cigarettes. The industry agreed then to

consult with HHS as it addressed any questions about specific ingredients.

7. What specific steps will industry take to cooperate with the Department of Health & Human Services in its review of the list?

ANSWER: The industry plans to participate in HHS' scientific review of the list. We are waiting for HHS to complete its initial evaluation of the list before determining what specific steps should be taken.

8. Don't consumers have the right to know what is in the products they buy?

ANSWER: The formulas of any number of consumer products are not treated as public information. These formulas often have great competitive value and require substantial time and expense to develop. The law therefore allows them to be treated as trade secrets. For example, the flavorings used in hundreds of foods and the fragrances used in cosmetics are treated as trade secrets.

9. Why aren't the ingredients used in cigarettes listed on the package?

ANSWER: As noted above, the identities of specific ingredients used in a particular brand of cigarettes are important trade secrets. The taste of a specific brand

may take years of time and millions of dollars to develop, and the law recognizes that such valuable information is entitled to confidential treatment.

10. The list of additives which has been supplied to HHS consists of those substances which are currently added to cigarettes. Have any substances been phased out of use in cigarettes since the request for this list was first made?

ANSWER: Like almost all consumer products, from frozen foods to breads or soft drinks, cigarettes undergo constant change as new brands are introduced and old brands are modified or phased out. Most of the modifications in the composition of cigarettes affect flavor constituents used in extremely small quantities. For many of these ingredients, the amount used annually is less than ten pounds for the entire industry. The major ingredients change less often, and many of them have been used for years.

The cigarette manufacturers have complied with the procedures adopted by HHS by submitting an initial list on April 2, 1986. An annual list will be submitted starting December 31, 1986. Any future changes in the ingredients used in cigarettes will be reflected in the lists submitted annually.

11. Are there any substances currently added to cigarettes sold only in other markets, particularly Third World markets, which are not used in cigarettes sold in the United States?

ANSWER: The Federal Cigarette Labeling and Advertising Act only requires that information be submitted concerning ingredients used in cigarettes sold in the United States, and we have not compiled information on cigarettes sold in other countries.

12. Are ingredients added to filters, and if so, what ingredients are added and what tests have been done to evaluate their safety?

ANSWER: The Federal Cigarette Labeling and Advertising Act only requires that information be submitted concerning ingredients added to the tobacco used in cigarettes sold in the United States. We have not compiled information on ingredients which might be added to other portions of the cigarette.

13. Are the ingredients used safe?

ANSWER: The companies do not believe that the addition to cigarettes of the ingredients on the list is harmful to smokers.

14. What evidence is there that the ingredients are safe?

ANSWER: Most of the ingredients are approved for use in foods by the Food and Drug Administration and are included in other lists of approved food, drug, and cosmetic ingredients in the United States and other countries. The inclusion of ingredients on these lists generally reflects a careful review of available data by scientists. Many of the ingredients are also included on approved lists of tobacco additives in Great Britain and Germany. These lists were prepared by scientists familiar with the uses of ingredients and information on their safety.

The companies have likewise reviewed available scientific evidence about the ingredients on the list. This includes test data found in the published scientific literature, as well as the results of unpublished research, on many of the ingredients. The safety of the ingredients used in foods and other articles for human consumption is supported by the available data. The data also indicate that the presence of ingredients in cigarettes does not materially affect the chemical composition of cigarette smoke.

15. Are there any substances which have historically been used as additives in cigarettes which are now regarded as hazardous?

ANSWER: In the past, the cigarette manufacturers have reviewed the questions that have arisen concerning ingredients. The companies do not believe that the addition to cigarettes of ingredients formerly or currently used has been harmful to smokers.

16. Why is there any reason to think that an ingredient is safe just because it has been used for a long period of time?

ANSWER: Longstanding use alone may not establish an ingredient's safety. However, most of the major ingredients used in large quantities in the production of cigarettes are either foods or are approved for use in foods or in the manufacture of food products. For these major ingredients, test data are available concerning both their food and tobacco applications. Despite extensive use, no evidence has been presented to establish that the addition of these ingredients to cigarettes is harmful to smokers.

17. What effect do ingredients have on non-smokers exposed to cigarette smoke?

ANSWER: As stated earlier, the companies do not believe that the addition to cigarettes of the ingredients on the

list is harmful to smokers. The companies likewise do not believe that the addition of ingredients to cigarettes is harmful to non-smokers who may be exposed to cigarette smoke.

18. Have each of the ingredients been tested to ensure that they are safe?

ANSWER: Since most of the ingredients are approved for use in foods, testing to determine their toxicity has been conducted, and the results have been made available to FDA. The tobacco companies have conducted additional testing on many ingredients and mixtures of ingredients which attempts to address the conditions encountered during cigarette smoking. Most of the ingredients used in the largest quantities and selected components of flavor mixtures have been tested.

19. What kinds of tests have been done on ingredients?

ANSWER: The need for testing, and the types of tests to be conducted, depend on a range of factors. There is no accepted testing methodology for evaluating ingredients. Nonetheless, depending on the circumstances, the research conducted includes inhalation studies, mouse skin painting studies, acute and chronic toxicity studies, and various *in vitro* studies. In addition, tests have been done to determine whether the presence of ingredients in

cigarettes affects the chemical composition of tobacco smoke.

20. The GRAS list and others list many of these ingredients as fit for human consumption, but fail to address the issue of potential dangers posed by the burning of these substances. What research has the industry done into the effects of pyrolysis on these substances?

ANSWER: Many of the ingredients are not pyrolyzed in cigarettes. Their boiling points are well below the temperature of a burning cigarette, and instead of burning they are transferred intact into cigarette smoke. Hence, data related to their food uses is useful in evaluating their effects when used in cigarettes.

For many other ingredients, overall usage levels indicate that pyrolysis data is of low priority. Only fifteen or so of the several hundred ingredients account for over 99% of the total amount of ingredients used. The rest are used in smaller quantities. Most of the ingredients are used as part of flavor mixtures purchased from flavor suppliers, and total industry usage of most of these ingredients is less than ten pounds a year. Moreover, many of the major ingredients are processing aids which remain in the final cigarette in extremely small and often undetectable amounts. For ingredients present in cigarettes in minimal quantities, the absence of significant exposure potential limits the need for pyrolysis testing.

Finally, research has shown that the pyrolysis of ingredients added to cigarettes does not significantly modify the composition of tobacco smoke. Tests have been done using research cigarettes containing much larger amounts of added ingredients than are used in commercial cigarettes. The smoke and/or the condensate from these cigarettes have been evaluated through animal and other tests that have been used in scientific research to investigate the biological effects of cigarette smoke. The tests have not demonstrated that the addition to cigarettes of the ingredients on the list is harmful to smokers.

21. Why haven't pyrolysis tests been run for all ingredients being used?

ANSWER: Many ingredients used in cigarettes are not pyrolized. They have relatively low boiling points, below the temperature of a burning cigarette, and they are transferred intact from the cigarette to the tobacco smoke. In fact, flavoring agents are often selected for their low boiling points, which assure that their flavoring properties are imparted to cigarette smoke. Hence, for these ingredients, pyrolysis tests are not relevant.

Pyrolysis testing on other types of ingredients is not called for in view of the manner in which they are used. Processing aids, for example, appear in the final

cigarette in extremely small and often undetectable amounts. In addition, a large number of ingredients used as components of flavor mixtures are likewise found in cigarettes in minuscule quantities.

22. Are there any studies which examine the effects of the ingredients when they have been inhaled?

ANSWER: Such studies have been done on some ingredients. The companies believe that these studies have not shown that the addition to cigarettes of the ingredients tested is harmful to smokers.

23. What value is any test other than a pyrolysis or inhalation test?

ANSWER: Scientists who evaluate the risks associated with substances often use tests conducted using one route of exposure to make judgments about other exposure conditions. For cigarette ingredients, inhalation or pyrolysis tests may often provide the most directly relevant data, but other tests can possess value.

24. Are you aware of any adverse health data generated either by the companies or available in the published literature?

ANSWER: Based on their review of available data and information, the companies do not believe that the addition of the ingredients to cigarettes is harmful to smokers.

25. Is more testing of ingredients planned?

ANSWER: The testing of ingredients has been conducted by individual companies on their own initiative. Companies will continue to conduct tests where they believe such tests are warranted.

26. You have noted that various bodies such as FEMA or FDA have approved the ingredients for use in foods. Why does that matter, since those organizations have not burned the ingredients?

ANSWER: The inclusion of the ingredients on lists of substances approved for food use by FEMA or FDA indicates that data have been reviewed by scientists who have concluded that the ingredient is suitable for human consumption. It may be appropriate to consider other types of data as well, but FDA's and FEMA's approval of the ingredients should receive considerable weight in evaluating exposure to the same substances through other routes.

27. Isn't it true that the committees which compiled the list of approved tobacco additives in Great Britain and in Germany did not have much information available to them about specific ingredients, but rather conducted a cursory examination?

ANSWER: These committees included independent scientists and government representatives. In developing a

list of approved substances, they examined the evidence they believed necessary to make an adequate safety evaluation, and concluded that the ingredients were suitable for use in cigarette manufacture. In some cases, the committees had available to them a large body of evidence, including test results. In other instances, a smaller amount of evidence may have been available, particularly for substances typically used in only small quantities. Nevertheless, we believe the review was independent and thorough.

28. What are the large-volume ingredients, why are they used, and what is known about their safety?

ANSWER: While comment on the identity of the major ingredients would be inappropriate, they generally have been used in cigarettes for decades and are extensively used in foods. Most of these ingredients serve as casing materials, humectants, or processing aids. As explained earlier, processing aids will remain in the final cigarettes only in extremely small and often undetectable amounts. Casing materials assist in producing a cigarette with a satisfactory taste and texture, and humectants serve to retain the moisture in cigarettes. Certain ingredients used as flavors in the more popular brands of cigarettes may also be used in larger quantities on an annual basis.

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A variety of tests have been done to evaluate the safety of the major ingredients. These include tests by the companies, as well as other work reflected in the published literature. Based on the available information, the companies do not believe that the addition to cigarettes of the ingredients on the list is harmful to smokers.

29. How many known carcinogens are on the list of ingredients which was submitted to HHS?

ANSWER: None of the substances on the list are considered potential human carcinogens by the National Toxicology Program (NTP), the International Agency for Research on Cancer (IARC), or other recognized organizations which evaluate the carcinogenic potential of substances.

30. Have the cigarette manufacturers ever used cloves, eugenol, or coumarin in their cigarettes?

ANSWER: Because specific ingredients are important trade secrets, the industry will not comment on whether these substances are being or have been used.

[Note -- this response will be used for all questions about specific ingredients.]

31. The list that has been released contains ingredients such as cloves, eugenol and coumarin. Is the industry really using these compounds?

ANSWER: The list which has been publicly released was prepared by HHS from submissions it received not only from Covington and Burling on behalf of the six major manufacturers, but from other manufacturers and importers of cigarettes as well. None of the specified ingredients were contained on the list submitted on behalf of the six major American tobacco companies.

32. A government scientist referred in a recent article in Mother Jones magazine to an unidentifiable "Compound X" which he had discovered in a cigarette. Does this compound really exist, and if so, what does the industry know about it?

ANSWER: The companies have no information about the specific compound which is referred to but not identified in the Mother Jones article.

33. Why is the industry using Covington and Burling as its spokesperson?

ANSWER: The Federal Cigarette Labeling and Advertising Act allows companies jointly to designate an agent to prepare a combined list of ingredients. Covington and Burling assisted the industry in earlier discussions with HHS concerning ingredients, and the companies asked

Covington and Burling to continue that representation in preparing the required list.

34. Isn't it true that you really do not know what effect these ingredients are having on the health of smokers?

ANSWER: The companies have reviewed the scientific literature on ingredients and, where appropriate, they have conducted their own tests to obtain additional scientific evidence. The companies do not believe that the addition to cigarettes of the ingredients on the list is harmful to smokers.

35. Don't ingredients simply add to the danger presented by cigarettes?

ANSWER: The industry does not believe that it has been established that cigarette smoking causes disease in smokers, or that the addition to cigarettes of the ingredients is harmful to smokers.

36. In the light of the nonchalant way in which the cigarette industry has used untested additives in billions of cigarettes every year, isn't it time that ingredients were brought under the aegis of the FDA?

Answer: HHS will evaluate the list of ingredients submitted by the industry and is charged by Congress with preparing a report on ingredients. We see no reason to create an additional review mechanism.

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Cipollone-Protective Order
Suggested Responses to Query

In the course of preparing the Cipollone suit, plaintiffs' attorneys obtained thousands of documents from the files of defendant companies. The defendant companies sought and were granted a protective order covering the documents from the presiding magistrate.

The magistrate's protective order was subsequently overturned by Judge Lee Sarokin of the U.S. District Court for the District of New Jersey. Judge Sarokin's order was later reversed on appeal by the U.S. Court of Appeals for the Third Circuit.

The documents in question are from company files covering a variety of subjects over a period of some 40 years. The companies' concerns about the documents arise quite naturally from fear that sentences or paragraphs from a number of documents covering a wide time span could be pieced together out of context and made to appear prejudicial.

Allegations stemming from the documents that might be made generally related to four subject areas:

- The Documents
- Lobbying
- Advertising
- Research

Following are statements which deal with the four general areas and which can be used as the basis for responding to questions:

- Response to Plaintiff's Allegations Concerning Documents.
- Response to Plaintiff's Allegations Concerning Lobbying.
- Response to Plaintiff's Allegations Concerning Advertising.
- Response to Plaintiff's Allegations Concerning Research.

DOCUMENTS STATEMENT

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PRIVILEGED AND CONFIDENTIAL 9/4/86

General Statement in Response to
Plaintiff's Allegations Concerning Documents

We are in the midst of prolonged and complicated litigation, in which all of the issues will be resolved in the courtroom. We firmly believe that the evidence should be heard and tested in court, at the time of trial, and not in a media campaign using selected bits and pieces of information out of context.

The selected documents released today were taken from private company records to which plaintiff's counsel has been given access. The release of these selected documents adds nothing to public knowledge concerning the smoking and health controversy. The out-of-context bits released today were culled from hundreds of thousands of documents covering a period of 40 years produced out of the tobacco companies' files for the purpose of this litigation.

The tobacco companies have gained information as well about plaintiffs through the same discovery process, the sole rationale for which is to obtain evidence for use in the courtroom. Such discovery material may not properly be used to create publicity, or to engage in a media campaign.

Since we are still in the process of collecting the evidence needed to tell the full story, it is inappropriate for us to engage in a media debate. We assure you that all of the appropriate evidence will be introduced at a trial, open to members of the press and public where each side will have an opportunity to tell its full story.

The real issue in these cases is personal choice. The tobacco companies believe that smoking is a matter about which individuals should be permitted to make their own decisions.

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LOBBYING STATEMENT

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PRIVILEGED AND CONFIDENTIAL 9/4/86

Statement in Response to Plaintiff's
Allegations Concerning Lobbying

To suggest that tobacco companies are somehow guilty of wrongdoing because they express their views to legislators is an insult to the American system of government itself. Lobbying is an accepted, time-honored and legitimate way for organizations or groups to make their views known to their legislators. The plaintiffs/claimants continue to follow their well established strategy of trying to move the trial of this case from the courtroom to the media. They are attempting to distract attention from the facts of the case by mischaracterizing private papers which were provided to them for their suit.

One of the principal constitutional rights provided by the democratic process is the right to talk to our elected representatives. The American Medical Association, the Catholic Conference of Bishops, the American Newspaper Publishers Association, the three TV networks, unions, industry groups and many others, as well as a number of anti-smoking groups, and groups of trial lawyers, maintain organizations to express their interests to Congress. Just as these groups do, tobacco companies also communicate with representatives to ensure that their views, and those of their employees, shareholders and customers are represented in public debate. We believe that people who choose to smoke should have the right to do so, free of harassment, and free of undue expense, and we are not embarrassed by that position.

We resent any attempt to portray rights shared by all American citizens as bribery or corruption simply because the one exercising those rights is a tobacco company.

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ADVERTISING STATEMENT

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PRIVILEGED AND CONFIDENTIAL 7/10/86

Statement in Response to Plaintiff's
Allegations Concerning Advertising

Any attempt to suggest to the media that tobacco companies have used advertising to manipulate the American people without their knowledge is completely without foundation in fact, and insults the good sense and intelligence of American consumers. Common sense suggests that advertising cannot persuade a non-smoker to smoke.

Cigarette ads do not say smoking is healthful. To the contrary, they all contain the Surgeon General's health warning. They do not urge non-smokers to start smoking, nor are they aimed at children. Independent research demonstrates that while cigarette ads are sometimes effective in motivating those who already smoke to try a new or different brand, they do not motivate non-smokers to take up smoking.

Recent statements by the plaintiff's attorneys indicate clearly their continued campaign to try to move the trial of their case from the courtroom to the media. Part of their strategy is an attack on cigarette advertising, but their thinking is basically flawed.

Cigarette advertisements show pleasant looking adults who enjoy smoking a particular brand of cigarettes. That is because there are millions of pleasant looking adults who do enjoy smoking. Using the same themes as the advertising for the thousands of other legal products sold in America, cigarette advertising seeks to encourage brand loyalty or a switch in brands.

The way in which cigarette companies advertise is a subject that Congress has debated exhaustively and which is monitored continuously by both Congress and the Federal Trade Commission.

The fundamental issue in these cases is personal choice. Those who choose to smoke in the face of health claims should have the right to do so and should be responsible for that choice.

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RESEARCH STATEMENT

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PRIVILEGED AND CONFIDENTIAL 7/10/86

Statement in Response to Plaintiff's
Allegations Concerning Research

The claim that the cigarette industry possesses the secret of cancer causation, and has conspired to hide it from the American people is simply untrue. It is difficult to think of any subject which has been aired as fully over as long a period of time as smoking and health. Health claims about smoking have been made since the days of King James the First and people cannot fairly plead ignorance of those claims.

The smoking and health issue has virtually been front page news since the early 1950's when epidemiological data first drew a statistical association between cigarette smoking and disease. Even prior to that time and in the absence of any substantial scientific support, there was a widespread public perception that cigarette smoking was accompanied by some risk. Children have been taught in school for at least four generations that cigarettes are bad for them.

It is unfortunate that mischaracterization of cigarette company research documents and the campaign engineered to disseminate to the media before trial selected private papers taken from company records, would seem to suggest an attempt to try cases in the media rather than in the court. Obviously we feel it improper to engage in the same tactics.

When the statistical link between cigarettes and cancer was suggested in the 1950's, the cigarette companies responded quickly and responsibly by devoting millions of dollars to financing independent arms-length research to pin down the causes of the disease. In spite of this research and research by other groups, no one has yet been able to demonstrate how any cancer, including lung cancer, begins or what causes it. These are questions with which scientists have grappled for decades. Various hypotheses have been suggested, but the issues are complex and the research presents enormous methodological problems.

It is essential to recognize that there is one fundamental issue underlying these suits and that will decide these cases at the time of trial: cigarette smoking is a matter of the smoker's personal choice made with full knowledge of the possible risks and benefits.

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SECTION 9 - ADDICTION CRITERIA

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Distinction Between Drug Addiction and Drug Habituation

Smokers and users of tobacco in other forms usually develop some degree of dependence upon the practice, some to the point where significant emotional disturbances occur if they are deprived of its use. The evidence indicates this dependence to be psychogenic in origin. In medical and scientific terminology the practice should be labeled *habituation* to distinguish it clearly from *addiction*, since the biological effects of tobacco, like coffee and other caffeine-containing beverages, betel morsel chewing and the like, are not comparable to those produced by morphine, alcohol, barbiturates, and many other potent addicting drugs. In fact, to make this distinction, the World Health Organization Expert Committee on Drugs Liable to Produce Addiction (35) created the following definitions which are accepted throughout the world as the basis for control of potentially dangerous drugs.

Drug Addiction

Drug addiction is a state of periodic or chronic intoxication produced by the repeated consumption of a drug (natural or synthetic). Its characteristics include:

1) An overpowering desire or need (compulsion) to continue taking the drug and to obtain it by any means;
2) A tendency to increase the dose;
3) A psychic (psychological) and generally a physical dependence on the effects of the drug;
4) Detrimental effect on the individual and on society.

Drug Habituation

Drug habituation (habit) is a condition resulting from the repeated consumption of a drug. Its characteristics include:

1) A desire (but not a compulsion) to continue taking the drug for the sense of improved well-being which it engenders;
2) Little or no tendency to increase the dose;
3) Some degree of psychic dependence on the effect of the drug, but absence of physical dependence and hence of an abstinence syndrome;
4) Detrimental effects, if any, primarily on the individual.

Tobacco Habit Characterized as Habituation

Psychogenic dependence is the common denominator of all drug habits and the primary drive which leads to initiation and relapse to chronic drug use or abuse (25). Although a pharmacologic drive is necessary it does not need to be a strong one or to produce profound subjective effects in order that habituation to the use of the crude material becomes a pattern of life. Besides tobacco, the use of caffeine in coffee, tea, and cocoa is the best example in the American culture. Another example, the chewing of the betel morsel, exists on a world scale comparable to tobacco and involves several hundred million individuals of both sexes and of all races, classes, and religions (17). The morsel contains arecoline from the areca nut, an ingredient of the mixture. It is a very mild stimulant of the nervous system which is ordinarily no more detectable than nicotine subjectively. The morsel is chewed from morning to night, from infancy to death, and creates a craving more powerful than that for tobacco. As with tobacco, oral gratification plays an important role in this habit.

Thus, correctly designating the chronic use of tobacco as habituation rather than addiction carries with it no implication that the habit may be broken easily. It does, however, carry an implication concerning the basic nature of the user and this distinction should be a clear one. It is generally accepted among psychiatrists that addiction to potent drugs is based upon serious personality defects from underlying psychologic or psychiatric disorders which may become manifest in other ways if the drugs are removed (33).

Even the most energetic and emotional campaigner against smoking and nicotine could find little support for the view that all those who use tobacco, coffee, tea, and cocoa are in need of mental care even though it may at some time in the future be shown that smokers and non-smokers have different psychologic characteristics.

Source - 1964 Surgeon General's Report on Smoking & Health

SECTION 10 - RESTATEMENT, TORTS, SECOND §402A

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C. Neither A nor B is liable to C in an action for negligence.

2. A, a retail dealer, sells to B a hot water bag purchased from a reputable manufacturer. A believes the bag to be in perfect condition, although he has not inspected it, but the bag is defective in that the stopper will not screw in securely. As a result of this defect, C, the minor son of B, is severely scalded by hot water that leaks out of the bag. A is not liable to B or to C in an action for negligence.

e. In many situations the seller who receives his goods from a reputable source of supply receives it with the firm conviction that it is free from defects; and where a chattel is of a type which is perfectly safe for use in the absence of defects, the seller who sells it with the reasonable belief that it is safe for use and represents it to be safe for use does not act negligently. Frequently, the manufacturer's literature and salesmen and his past record of sending the seller perfectly made chattels create a reasonable belief in the seller's mind that the particular chattel he is selling is made perfectly. When the seller reasonably believes that the chattel is safe, his representation in good faith to that effect is neither fraudulent, reckless, nor negligent.

Illustration:

3. A, a retail dealer, sells to B a defective gas heater, obtained from a reputable manufacturer, which A believes to be in perfect condition, although he has not inspected it. In making the sale, and in response to B's inquiry, A says, "This heater can be used with perfect safety." The heater when used emits poisonous fumes, injuring B. A is not liable to B in an action for negligence.

TOPIC 5. STRICT LIABILITY

§ 402 A. Special Liability of Seller of Product for Physical Harm to User or Consumer

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm

See Appendix for Reporter's Notes, Court Citations, and Cross References

thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

See Reporter's Notes.

Caveat:

The Institute expresses no opinion as to whether the rules stated in this Section may not apply

(1) to harm to persons other than users or consumers;

(2) to the seller of a product expected to be processed or otherwise substantially changed before it reaches the user or consumer; or

(3) to the seller of a component part of a product to be assembled.

Comment:

a. This Section states a special rule applicable to sellers of products. The rule is one of strict liability, making the seller subject to liability to the user or consumer even though he has exercised all possible care in the preparation and sale of the product. The Section is inserted in the Chapter dealing with the negligence liability of suppliers of chattels, for convenience of reference and comparison with other Sections dealing with negligence. The rule stated here is not exclusive, and does not preclude liability based upon the alternative ground of negligence of the seller, where such negligence can be proved.

b. History. Since the early days of the common law those engaged in the business of selling food intended for human consumption have been held to a high degree of responsibility for their products. As long ago as 1266 there were enacted special criminal statutes imposing penalties upon victualers, vintners,

See Appendix for Reporter's Notes, Court Citations, and Cross References

brewers, butchers, cooks, and other persons who supplied "corrupt" food and drink. In the earlier part of this century this ancient attitude was reflected in a series of decisions in which the courts of a number of states sought to find some method of holding the seller of food liable to the ultimate consumer even though there was no showing of negligence on the part of the seller. These decisions represented a departure from, and an exception to, the general rule that a supplier of chattels was not liable to third persons in the absence of negligence or privity of contract. In the beginning, these decisions displayed considerable ingenuity in evolving more or less fictitious theories of liability to fit the case. The various devices included an agency of the intermediate dealer or another to purchase for the consumer, or to sell for the seller; a theoretical assignment of the seller's warranty to the intermediate dealer; a third party beneficiary contract; and an implied representation that the food was fit for consumption because it was placed on the market, as well as numerous others. In later years the courts have become more or less agreed upon the theory of a "warranty" from the seller to the consumer, either "running with the goods" by analogy to a covenant running with the land, or made directly to the consumer. Other decisions have indicated that the basis is merely one of strict liability in tort, which is not dependent upon either contract or negligence.

Recent decisions, since 1950, have extended this special rule of strict liability beyond the seller of food for human consumption. The first extension was into the closely analogous cases of other products intended for intimate bodily use, where, for example, as in the case of cosmetics, the application to the body of the consumer is external rather than internal. Beginning in 1958 with a Michigan case involving cinder building blocks, a number of recent decisions have discarded any limitation to intimate association with the body, and have extended the rule of strict liability to cover the sale of any product which, if it should prove to be defective, may be expected to cause physical harm to the consumer or his property.

c. On whatever theory, the justification for the strict liability has been said to be that the seller, by marketing his product for use and consumption, has undertaken and assumed a special responsibility toward any member of the consuming public who may be injured by it; that the public has the right to and does expect, in the case of products which it needs and for which

See Appendix for Reporter's Notes, Court Citations, and Cross References

it is forced to rely upon the seller, that reputable sellers will stand behind their goods; that public policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained; and that the consumer of such products is entitled to the maximum of protection at the hands of someone, and the proper persons to afford it are those who market the products.

d. The rule stated in this Section is not limited to the sale of food for human consumption, or other products for intimate bodily use, although it will obviously include them. It extends to any product sold in the condition, or substantially the same condition, in which it is expected to reach the ultimate user or consumer. Thus the rule stated applies to an automobile, a tire, an airplane, a grinding wheel, a water heater, a gas stove, a power tool, a riveting machine, a chair, and an insecticide. It applies also to products which, if they are defective, may be expected to and do cause only "physical harm" in the form of damage to the user's land or chattels, as in the case of animal food or a herbicide.

e. Normally the rule stated in this Section will be applied to articles which already have undergone some processing before sale, since there is today little in the way of consumer products which will reach the consumer without such processing. The rule is not, however, so limited, and the supplier of poisonous mushrooms which are neither cooked, canned, packaged, nor otherwise treated is subject to the liability here stated.

f. Business of selling. The rule stated in this Section applies to any person engaged in the business of selling products for use or consumption. It therefore applies to any manufacturer of such a product, to any wholesale or retail dealer or distributor, and to the operator of a restaurant. It is not necessary that the seller be engaged solely in the business of selling such products. Thus the rule applies to the owner of a motion picture theatre who sells popcorn or ice cream, either for consumption on the premises or in packages to be taken home.

The rule does not, however, apply to the occasional seller of food or other such products who is not engaged in that activity as a part of his business. Thus it does not apply to the housewife who, on one occasion, sells to her neighbor a jar of jam or a pound of sugar. Nor does it apply to the owner of an

automobile who, on one occasion, sells it to his neighbor, or even sells it to a dealer in used cars, and this even though he is fully aware that the dealer plans to resell it. The basis for the rule is the ancient one of the special responsibility for the safety of the public undertaken by one who enters into the business of supplying human beings with products which may endanger the safety of their persons and property, and the forced reliance upon that undertaking on the part of those who purchase such goods. This basis is lacking in the case of the ordinary individual who makes the isolated sale, and he is not liable to a third person, or even to his buyer, in the absence of his negligence. An analogy may be found in the provision of the Uniform Sales Act, § 15, which limits the implied warranty of merchantable quality to sellers who deal in such goods; and in the similar limitation of the Uniform Commercial Code, § 2–314, to a seller who is a merchant. This Section is also not intended to apply to sales of the stock of merchants out of the usual course of business, such as execution sales, bankruptcy sales, bulk sales, and the like.

g. Defective condition. The rule stated in this Section applies only where the product is, at the time it leaves the seller's hands, in a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him. The seller is not liable when he delivers the product in a safe condition, and subsequent mishandling or other causes make it harmful by the time it is consumed. The burden of proof that the product was in a defective condition at the time that it left the hands of the particular seller is upon the injured plaintiff; and unless evidence can be produced which will support the conclusion that it was then defective, the burden is not sustained.

Safe condition at the time of delivery by the seller will, however, include proper packaging, necessary sterilization, and other precautions required to permit the product to remain safe for a normal length of time when handled in a normal manner.

h. A product is not in a defective condition when it is safe for normal handling and consumption. If the injury results from abnormal handling, as where a bottled beverage is knocked against a radiator to remove the cap, or from abnormal preparation for use, as where too much salt is added to food, or from abnormal consumption, as where a child eats too much candy and is made ill, the seller is not liable. Where, however, he has reason to anticipate that danger may result from a particular use, as where a drug is sold which is safe only in limited doses, he

See Appendix for Reporter's Notes, Court Citations, and Cross References

may be required to give adequate warning of the danger (see Comment *j*), and a product sold without such warning is in a defective condition.

The defective condition may arise not only from harmful ingredients, not characteristic of the product itself either as to presence or quantity, but also from foreign objects contained in the product, from decay or deterioration before sale, or from the way in which the product is prepared or packed. No reason is apparent for distinguishing between the product itself and the container in which it is supplied; and the two are purchased by the user or consumer as an integrated whole. Where the container is itself dangerous, the product is sold in a defective condition. Thus a carbonated beverage in a bottle which is so weak, or cracked, or jagged at the edges, or bottled under such excessive pressure that it may explode or otherwise cause harm to the person who handles it, is in a defective and dangerous condition. The container cannot logically be separated from the contents when the two are sold as a unit, and the liability stated in this Section arises not only when the consumer drinks the beverage and is poisoned by it, but also when he is injured by the bottle while he is handling it preparatory to consumption.

i. Unreasonably dangerous. The rule stated in this Section applies only where the defective condition of the product makes it unreasonably dangerous to the user or consumer. Many products cannot possibly be made entirely safe for all consumption, and any food or drug necessarily involves some risk of harm, if only from over-consumption. Ordinary sugar is a deadly poison to diabetics, and castor oil found use under Mussolini as an instrument of torture. That is not what is meant by "unreasonably dangerous" in this Section. The article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics. Good whiskey is not unreasonably dangerous merely because it will make some people drunk, and is especially dangerous to alcoholics; but bad whiskey, containing a dangerous amount of fusel oil, is unreasonably dangerous. Good tobacco is not unreasonably dangerous merely because the effects of smoking may be harmful; but tobacco containing something like marijuana may be unreasonably dangerous. Good butter is not unreasonably dangerous merely because, if such be the case, it deposits cholesterol in the arteries

See Appendix for Reporter's Notes, Court Citations, and Cross References

and leads to heart attacks; but bad butter, contaminated with poisonous fish oil, is unreasonably dangerous.

j. Directions or warning. In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use. The seller may reasonably assume that those with common allergies, as for example to eggs or strawberries, will be aware of them, and he is not required to warn against them. Where, however, the product contains an ingredient to which a substantial number of the population are allergic, and the ingredient is one whose danger is not generally known, or if known is one which the consumer would reasonably not expect to find in the product, the seller is required to give warning against it, if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the ingredient and the danger. Likewise in the case of poisonous drugs, or those unduly dangerous for other reasons, warning as to use may be required.

But a seller is not required to warn with respect to products, or ingredients in them, which are only dangerous, or potentially so, when consumed in excessive quantity, or over a long period of time, when the danger, or potentiality of danger, is generally known and recognized. Again the dangers of alcoholic beverages are an example, as are also those of foods containing such substances as saturated fats, which may over a period of time have a deleterious effect upon the human heart.

Where warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous.

k. Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and

See Appendix for Reporter's Notes, Court Citations, and Cross References

warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

l. User or consumer. In order for the rule stated in this Section to apply, it is not necessary that the ultimate user or consumer have acquired the product directly from the seller, although the rule applies equally if he does so. He may have acquired it through one or more intermediate dealers. It is not even necessary that the consumer have purchased the product at all. He may be a member of the family of the final purchaser, or his employee, or a guest at his table, or a mere donee from the purchaser. The liability stated is one in tort, and does not require any contractual relation, or privity of contract, between the plaintiff and the defendant.

"Consumers" include not only those who in fact consume the product, but also those who prepare it for consumption; and the housewife who contracts tularemia while cooking rabbits for her husband is included within the rule stated in this Section, as is also the husband who is opening a bottle of beer for his wife to drink. Consumption includes all ultimate uses for which the product is intended, and the customer in a beauty shop to whose hair a permanent wave solution is applied by the shop is a consumer. "User" includes those who are passively enjoying the benefit of the product, as in the case of passengers in automobiles or airplanes, as well as those who are utilizing it for the purpose of doing work upon it, as in the case of an employee of the ultimate buyer who is making repairs upon the automobile which he has purchased.

See Appendix for Reporter's Notes, Court Citations, and Cross References

Illustration:

1. A manufactures and packs a can of beans, which he sells to B, a wholesaler. B sells the beans to C, a jobber, who resells it to D, a retail grocer. E buys the can of beans from D, and gives it to F. F serves the beans at lunch to G, his guest. While eating the beans, G breaks a tooth, on a pebble of the size, shape, and color of a bean, which no reasonable inspection could possibly have discovered. There is satisfactory evidence that the pebble was in the can of beans when it was opened. Although there is no negligence on the part of A, B, C, or D, each of them is subject to liability to G. On the other hand E and F, who have not sold the beans, are not liable to G in the absence of some negligence on their part.

m. "Warranty." The liability stated in this Section does not rest upon negligence. It is strict liability, similar in its nature to that covered by Chapters 20 and 21. The basis of liability is purely one of tort.

A number of courts, seeking a theoretical basis for the liability, have resorted to a "warranty," either running with the goods sold, by analogy to covenants running with the land, or made directly to the consumer without contract. In some instances this theory has proved to be an unfortunate one. Although warranty was in its origin a matter of tort liability, and it is generally agreed that a tort action will still lie for its breach, it has become so identified in practice with a contract of sale between the plaintiff and the defendant that the warranty theory has become something of an obstacle to the recognition of the strict liability where there is no such contract. There is nothing in this Section which would prevent any court from treating the rule stated as a matter of "warranty" to the user or consumer. But if this is done, it should be recognized and understood that the "warranty" is a very different kind of warranty from those usually found in the sale of goods, and that it is not subject to the various contract rules which have grown up to surround such sales.

The rule stated in this Section does not require any reliance on the part of the consumer upon the reputation, skill, or judgment of the seller who is to be held liable, nor any representation or undertaking on the part of that seller. The seller is strictly liable although, as is frequently the case, the consumer does not even know who he is at the time of consumption.

See Appendix for Reporter's Notes, Court Citations, and Cross References

The rule stated in this Section is not governed by the provisions of the Uniform Sales Act, or those of the Uniform Commercial Code, as to warranties; and it is not affected by limitations on the scope and content of warranties, or by limitation to "buyer" and "seller" in those statutes. Nor is the consumer required to give notice to the seller of his injury within a reasonable time after it occurs, as is provided by the Uniform Act. The consumer's cause of action does not depend upon the validity of his contract with the person from whom he acquires the product, and it is not affected by any disclaimer or other agreement, whether it be between the seller and his immediate buyer, or attached to and accompanying the product into the consumer's hands. In short, "warranty" must be given a new and different meaning if it is used in connection with this Section. It is much simpler to regard the liability here stated as merely one of strict liability in tort.

n. Contributory negligence. Since the liability with which this Section deals is not based upon negligence of the seller, but is strict liability, the rule applied to strict liability cases (see § 524) applies. Contributory negligence of the plaintiff is not a defense when such negligence consists merely in a failure to discover the defect in the product, or to guard against the possibility of its existence. On the other hand the form of contributory negligence which consists in voluntarily and unreasonably proceeding to encounter a known danger, and commonly passes under the name of assumption of risk, is a defense under this Section as in other cases of strict liability. If the user or consumer discovers the defect and is aware of the danger, and nevertheless proceeds unreasonably to make use of the product and is injured by it, he is barred from recovery.

Comment on Caveat:

o. Injuries to non-users and non-consumers. Thus far the courts, in applying the rule stated in this Section, have not gone beyond allowing recovery to users and consumers, as those terms are defined in Comment *l*. Casual bystanders, and others who may come in contact with the product, as in the case of employees of the retailer, or a passer-by injured by an exploding bottle, or a pedestrian hit by an automobile, have been denied recovery. There may be no essential reason why such plaintiffs should not be brought within the scope of the protection afforded, other than that they do not have the same reasons for expecting such pro-

tection as the consumer who buys a marketed product; but the social pressure which has been largely responsible for the development of the rule stated has been a consumers' pressure, and there is not the same demand for the protection of casual strangers. The Institute expresses neither approval nor disapproval of expansion of the rule to permit recovery by such persons.

p. Further processing or substantial change. Thus far the decisions applying the rule stated have not gone beyond products which are sold in the condition, or in substantially the same condition, in which they are expected to reach the hands of the ultimate user or consumer. In the absence of decisions providing a clue to the rules which are likely to develop, the Institute has refrained from taking any position as to the possible liability of the seller where the product is expected to, and does, undergo further processing or other substantial change after it leaves his hands and before it reaches those of the ultimate user or consumer.

It seems reasonably clear that the mere fact that the product is to undergo processing, or other substantial change, will not in all cases relieve the seller of liability under the rule stated in this Section. If, for example, raw coffee beans are sold to a buyer who roasts and packs them for sale to the ultimate consumer, it cannot be supposed that the seller will be relieved of all liability when the raw beans are contaminated with arsenic, or some other poison. Likewise the seller of an automobile with a defective steering gear which breaks and injures the driver, can scarcely expect to be relieved of the responsibility by reason of the fact that the car is sold to a dealer who is expected to "service" it, adjust the brakes, mount and inflate the tires, and the like, before it is ready for use. On the other hand, the manufacturer of pigiron, which is capable of a wide variety of uses, is not so likely to be held to strict liability when it turns out to be unsuitable for the child's tricycle into which it is finally made by a remote buyer. The question is essentially one of whether the responsibility for discovery and prevention of the dangerous defect is shifted to the intermediate party who is to make the changes. No doubt there will be some situations, and some defects, as to which the responsibility will be shifted, and others in which it will not. The existing decisions as yet throw no light upon the questions, and the Institute therefore expresses neither approval nor disapproval of the seller's strict liability in such a case.

See Appendix for Reporter's Notes, Court Citations, and Cross References

q. Component parts. The same problem arises in cases of the sale of a component part of a product to be assembled by another, as for example a tire to be placed on a new automobile, a brake cylinder for the same purpose, or an instrument for the panel of an airplane. Again the question arises, whether the responsibility is not shifted to the assembler. It is no doubt to be expected that where there is no change in the component part itself, but it is merely incorporated into something larger, the strict liability will be found to carry through to the ultimate user or consumer. But in the absence of a sufficient number of decisions on the matter to justify a conclusion, the Institute expresses no opinion on the matter.

§ 402 B. Misrepresentation by Seller of Chattels to Consumer

One engaged in the business of selling chattels who, by advertising, labels, or otherwise, makes to the public a misrepresentation of a material fact concerning the character or quality of a chattel sold by him is subject to liability for physical harm to a consumer of the chattel caused by justifiable reliance upon the misrepresentation, even though

(a) it is not made fraudulently or negligently, and

(b) the consumer has not bought the chattel from or entered into any contractual relation with the seller.

See Reporter's Notes.

Caveat:

The Institute expresses no opinion as to whether the rule stated in this Section may apply

(1) where the representation is not made to the public, but to an individual, or

(2) where physical harm is caused to one who is not a consumer of the chattel.

Comment:

a. The rule stated in this Section is one of strict liability for physical harm to the consumer, resulting from a misrepresentation of the character or quality of the chattel sold, even though the misrepresentation is an innocent one, and not made fraudulently or negligently. Although the Section deals with misrepresentation, it is inserted here in order to complete the

RESTATEMENT OF THE LAW
OF
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APPENDIX

DIVISION TWO

NEGLIGENCE

CHAPTER 14

LIABILITY OF PERSONS SUPPLYING CHATTELS FOR THE USE OF OTHERS (Continued)

TOPIC 5. STRICT LIABILITY

§ 402 A. Special Liability of Seller of Product for Physical Harm to User or Consumer.

REPORTER'S NOTES

This Section has been added to the first Restatement.

1. The Section is supported, as to food and drink, by decisions in the following jurisdictions:

Arizona. Crystal Coca-Cola Bottling Co. v. Cathey, 83 Ariz. 163, 317 P.2d 1094 (1957); see Eisenbeiss v. Payne, 42 Ariz. 262, 25 P.2d 162 (1933).

California. Klein v. Duchess Sandwich Co., 14 Cal. 2d 272, 93

Cit.—cited; fol.—followed; quot.—quoted; sup.—support.
A complete list of abbreviations faces page 1.

P.2d 799 (1939); Vaccarezza v. Sanguinetti, 71 Cal. App. 2d 687, 163 P.2d 470 (1945); Medeiros v. Coca-Cola Bottling Co., 57 Cal. App. 2d 707, 135 P.2d 676 (1943).

Florida. Blanton v. Cudahy Packing Co., 154 Fla. 872, 19 So. 2d 313 (1944); Florida Coca-Cola Bottling Co. v. Jordan, 62 So. 2d 910 (Fla. 1953); Canada Dry Bottling Co. of Florida v. Shaw, 118 So. 2d 840 (Fla. App. 1960).

Illinois. Patargias v. Coca-Cola Bottling Co., 332 Ill. App. 117, 74 N.E.2d 162 (1947); Blarjeske v. Thompson's Restaurant Co., 325 Ill. App. 189, 58 N.E.2d 320 (1945); Welter v. Bowman Dairy Co., 318 Ill. App. 305, 47 N.E.2d 739 (1943); Heimsoth v. Falstaff Brewing Corp., 1 Ill. App. 2d 28, 116 N.E.2d 193 (1953).

Iowa. Davis v. Van Camp Packing Co., 189 Iowa 775, 176 N.W. 882, 17 A.L.R. 649 (1920); Anderson v. Tyler, 223 Iowa 1033, 274 N.W. 48 (1937).

Kansas. Parks v. C. C. Yost Pie Co., 93 Kan. 334, 144 P. 202, L.R.A. 1915C, 179, 7 N.C.C.A. 100 (1914); Challis v. Hartloff, 136 Kan. 823, 18 P.2d 199 (1933); Swengel v. F. & E. Wholesale Grocery Co., 147 Kan. 555, 77 P.2d 830, 4 N.C.C.A. N.S. 709 (1938); Nichols v. Nold, 174 Kan. 613, 258 P.2d 317, 38 A.L.R.2d 837 (1953); Simmons v. Wichita Coca-Cola Bottling Co., 181 Kan. 35, 309 P. 2d 633 (1957); Cernes v. Pittsburg Coca-Cola Bottling Co., 183 Kan. 758, 332 P.2d 258, 77 A.L.R. 2d 208 (1958); Rupp v. Norton Coca-Cola Bottling Co., 187 Kan. 390, 357 P.2d 802 (1960); Connell v. Norton Coca-Cola Bottling Co., 187 Kan. 393, 357 P.2d 804 (1960).

Louisiana. Le Blanc v. Louisiana Coca-Cola Bottling Co., 221 La. 919, 60 So. 2d 873 (1952); Miller v. Louisiana Coca-Cola Bottling Co., 70 So. 2d 409 (La. App. 1954).

Michigan. Manzoni v. Detroit Coca-Cola Bottling Co., 363 Mich. 235, 109 N.W.2d 918 (1961).

Mississippi. Jackson Coca-Cola Bottling Co. v. Chapman, 106 Miss. 864, 64 So. 791 (1914); Rainwater v. Hattiesburg Coca-Cola Bottling Co., 131 Miss. 315, 95 So. 444 (1923); Coca-Cola Bottling Works v. Lyons, 145 Miss. 876, 111 So. 305 (1927); Chenault v. Houston Coca-Cola Bottling Co., 151 Miss. 366, 118 So. 177 (1928); Coca-Cola Bottling Works v. Simpson, 158 Miss. 390, 130 So. 479, 72 A.L.R. 143 (1930); Bufkin v. Grisham, 157 Miss. 746, 128 So. 563 (1930); Curtiss Candy Co. v. Johnson, 163 Miss. 426, 141 So. 762 (1932); Biedenharn Candy Co. v. Moore, 184 Miss. 721, 186 So. 628 (1939).

Missouri. Madouros v. Kansas City Coca-Cola Bottling Co., 230 Mo. App. 275, 90 S.W.2d 445 (1936); Nemela v. Coca-Cola Bottling Co., 104 S.W.2d 773 (Mo. App. 1937); McNicholas v. Continental Baking Co., 112 S.W.2d 849 (Mo. App. 1938); Carter v. St. Louis Dairy Co., 139 S.W.2d 1025 (Mo. App. 1940); Helms v. General Baking Co., 164 S.W.2d 150 (Mo. App. 1942); Foley v. Coca-Cola Bottling Co., 215 S.W. 2d 314 (Mo. App. 1948).

Nebraska. Asher v. Coca-Cola Bottling Co., 172 Neb. 855, 112 N.W.2d 252 (1961).

New Jersey. There are as yet no food cases, but in Henningsen v. Bloomfield Motors, 32 N.J. 358, 161 A.2d 69, 75 A.L.R.2d 1 (1960), where strict liability was applied to an automobile, the food rule apparently was approved.

See also cases under division, chapter, topic, title, and subtitle that includes section under examination.

New York. This state has gone beyond food, in Goldberg v. Kollsman Instrument Corp., 12 N.Y.2d 432, 191 N.E.2d 81 (1963).

Ohio. Ward Baking Co. v. Trizzino, 27 Ohio App. 475, 161 N.E. 557 (1928); Tennebaum v. Pendergast, 55 Ohio L. Abs. 235, 90 N.E.2d 453 (C.P. 1949); Mahoney v. Shaker Square Beverages, 46 Ohio Op. 250, 64 Ohio L. Abs. 200, 102 N.E.2d 281 (Com. Pl. 1951).

Pennsylvania. At first this state relied on a pure food statute, said to be declaratory of the common law. Catani v. Swift & Co., 251 Pa. 52, 95 A. 931, L.R.A. 1917B, 1272 (1915), error dismissed, 241 U.S. 690, 36 S. Ct. 554, 60 L. Ed. 1238; Nock v. Coca-Cola Bottling Works, 102 Pa. Super. 515, 156 A. 537 (1931). Later cases have ceased to mention it. Bilk v. Abbott's Dairies, 147 Pa. Super. 39, 23 A.2d 842 (1941); Caskie v. Coca-Cola Bottling Co., 373 Pa. 614, 96 A.2d 901 (1953); see Bonker v. Ingersoll Products Co., 132 F. Supp. 5 (D. Mass. 1955).

Puerto Rico. Coca-Cola Bottling Co. v. Negron Torres, 255 F.2d 149 (1 Cir. 1958); Ponce De Leon v. Coca-Cola Bottling Co., 75 F. Supp. 966 (D. Puerto Rico 1948).

Tennessee. Probably. General Motors Corp. v. Dodson, 47 Tenn. App. 428, 338 S.W.2d 655 (1960), imposed strict liability as to an automobile, which appears to indicate a change in the law.

Texas. Jacob E. Decker & Sons v. Capps, 139 Tex. 609, 164 S.W.2d 828, 142 A.L.R. 1479 (1942); Griggs Canning Co. v. Josey, 139 Tex. 623, 164 S.W.2d 835, 142 A.L.R. 1424 (1942), answer conformed to, 165 S.W.2d 203 (Tex. Civ. App.); Coca-Cola Bottling Co. v. Smith, 97 S.W.2d 761 (Tex. Civ. App. 1936); Coca-Cola Bottling Co. v. Burgess, 195 S.W.2d 879 (Tex. Civ. App. 1946), refused no reversible error; Amarillo Coca-Cola Bottling Co. v. Loudder, 207 S.W.2d 632 (Tex. Civ. App. 1947); Sweeney v. Cain, 243 S.W.2d 874 (Tex. Civ. App. 1951); Campbell Soup Co. v. Ryan, 338 S.W.2d 821 (Tex. Civ. App. 1959).

Virginia. Swift & Co. v. Wells, 201 Va. 213, 110 S.E.2d 203 (1959).

Washington. Nelson v. West Coast Dairy Co., 5 Wash.2d 284, 105 P.2d 76, 130 A.L.R. 606 (1940); La Hue v. Coca-Cola Bottling, Inc., 50 Wash.2d 645, 314 P. 2d 421 (1957); see Geisness v. Scow Bay Packing Co., 16 Wash. 2d 1, 132 P.2d 740 (1942); Mazetti v. Armour & Co., 75 Wash. 622, 135 P. 633, 48 L.R.A. N.S. 213, Ann. Cas. 1915C, 140 (1913).

2. The following states now reach the same result, as to food and drink, under statutes which provide for strict liability, or are construed to have that effect:

Connecticut. Conn. Gen. Stat. § 2161c (Supp. 1953). A food warranty to "all persons for whom such food and drink is intended."

Georgia. Donaldson v. Great A. & P. Tea Co., 186 Ga. 870, 199 S.E. 213, 128 A.L.R. 456 (1938), answer conformed to, 59 Ga. App. 79, 200 S.E. 498.

Minnesota. Meshbesher v. Channellene Oil & Mfg. Co., 107 Minn. 104, 119 N.W. 428, 131 Am. St. Rep. 441 (1909).

Montana. Bolitho v. Safeway Stores, 109 Mont. 213, 95 P.2d 443 (1939).

South Carolina. Culbertson v. Coca-Cola Bottling Co., 157 S.C.

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A complete list of abbreviations faces page 1.

352, 154 S.E. 424 (1930); Hollis v. Armour & Co., 190 S.C. 170, 2 S.E.2d 681 (1939); McKenzie v. Peoples Baking Co., 205 S.C. 149, 31 S.E.2d 154 (1944).

3. The products to which liability has been extended beyond those for "intimate bodily use," are as follows:

Animal food: McAfee v. Cargill, Inc., 121 F. Supp. 5 (S.D. Cal. 1954), dog food; Midwest Game Co. v. M.F.A. Milling Co., 330 S.W. 2d 547 (Mo. 1959), fish food.

Automobiles: Jaxmot v. Ford Motor Co., 191 Pa. Super. 422, 156 A.2d 559 (1959), truck; Henningsen v. Bloomfield Motors, 32 N.J. 158, 161 A.2d 69 (1960); Pabon v. Hackensack Auto Sales, Inc., 63 N.J. Super. 476, 164 A.2d 773 (1960); Courtois v. General Motors Corp., 37 N.J. 525, 182 A.2d 545 (1962); General Motors Corp. v. Dodson, 338 S.W.2d 655 (Tenn. App. 1960); State Farm Mut. Automobile Ins. Co. v. Anderson-Weber, Inc., 110 N.W.2d 449 (Iowa 1961); Thompson v. Reedman, 199 F. Supp. 120 (E.D. Pa. 1961); Picker X-Ray Corp. v. General Motors Corp., 185 A.2d 919 (Mun. App. D.C. 1962); Duckworth v. Ford Motor Co., 211 F. Supp. 888 (E. D. Pa. 1962); Connolly v. Hagi, 24 Conn. Super. 198, 188 A.2d 884 (1963); Vandermark v. Ford Motor Co., 33 Cal. Rptr. 175 (Cal. App. 1963).

Tires: B. F. Goodrich Co. v. Hammond, 269 F.2d 501 (10 Cir. 1959). Cf. Hart v. Goodyear Tire & Rubber Co., 214 F. Supp. 817 (N.D. Ind. 1963), extension of "privity" to purchaser's employee.

Steering gear: Magee v. General Motors, 124 F. Supp. 606 (W. D. Pa. 1954).

Airplanes: Goldberg v. Kollsman Instrument Corp., 12 N.Y. 2d 432, 191 N.E. 2d 81 (1963); Middleton v. United Aircraft Corp., 204 F. Supp. 856 (S.D.N.Y 1960); Hinton v. Republic Aviation Corp., 180 F. Supp. 31 (S. D. N.Y. 1959), California law; Siegel v. Braniff Airways, 204 F. Supp. 865 (S.D. N.Y. 1960), Michigan law; Ewing v. Lockheed Aircraft Corp., 202 F.Supp. 216 (D. Minn. 1962), Texas law; King v. Douglas Aircraft Co., 159 So.2d 108 (Fla. App. 1963).

Airplane instrument: Taylerson v. American Airlines, 183 F. Supp. 882 (S.D.N.Y.) 1960).

Grinding wheels: Di Vello v. Gardner Machine Co., 46 Ohio Op. 161, 102 N.E.2d 285 (1951), possibly overruled, possibly not; Peterson v. Lamb Rubber Co., 54 Cal. 2d 339, 353 P.2d 575 (1959); Jabukowski v. Minnesota Mining & Mfg. Co., 193 A.2d 275 (N.J. Super. 1963).

Cinder building blocks: Spence v. Three Rivers Builders & Masonry Supply, Inc., 353 Mich. 120, 90 N.W. 2d 873 (1958).

Electric cable: Continental Copper & Steel Industries v. E. C. "Red" Cornelius, Inc., 102 So. 2d 40 (Fla. App. 1958).

Insecticide spray: McQuaide v. Bridgeport Brass Co., 190 F. Supp. 252 (D. Conn. 1960).

Herbicide: See Spada v. Stauffer Chemical Co., 195 F. Supp. 819 (D. Or. 1961).

Combination power tool: Greenman v. Yuba Power Products, Inc., 377 P.2d 899 (Cal. 1963).

Power golf cart: Simpson v. Powered Products of Michigan, Inc., 24 Conn.Super. 409, 192 A. 2d 555 (1963).

Children's playground equip-

See also cases under division, chapter, topic, title, and subtitle that includes section under examination.

...berg v. Kolls-...rp., 12 N.Y. 2d ...1 (1963); Mid-...d Aircraft Corp., ...856 (S.D.N.Y ...Republic Avia-...Supp. 31 (S. D. ...fornia law; Siegel ...ays, 204 F. Supp. ...960), Michigan ...kheed Aircraft ...pp. 216 (D. Minn. ...; King v. Douglas ...So.2d 108 (Fla.

...*rument:* Tayler-...n Airlines, 183 F. ...M.) 1960).

...*:* Di Vello v. ...e Co., 46 Ohio Op. ...285 (1951), pos-...sibly not; Pe-...r Co., 54 Cal. ...575 (1959); Minnesota Mining ...A.2d 275 (N.J.

...*ng blocks:* Spence ...Builders & Ma-...353 Mich. 120, ...1958).

...*ble:* Continental Industries v. E. C. ...Inc., 102 So. 2d ...8).

...*ory:* McQuaide v. ...ass Co., 190 F. ...nn. 1960).

...Spada v. Stauf-...Co., 195 F. Supp. ...61).

...*wer tool:* Green-...ower Products, ...9 (Cal. 1963).

...*cart:* Simpson v. ...s of Michigan, ...per. 409, 192 A.

...*playground equip-*...ad subtitle

...*ment:* McBurnette v. Playground Equipment Corp., 137 So. 2d 563 (Fla. 1962).

Chair: Thomas v. Leary, 15 App. Div. 2d 438, 225 N.Y.S.2d 137 (1962).

Riveting machine: Hoffman v. Cox, 35 Misc. 2d 103, 229 N.Y.S. 2d 485 (1962).

Water heater: Deveny v. Rheem Mfg. Co., 319 F.2d 124 (2 Cir. 1963), Vermont law.

Gas stove: Morrow v. Caloric Appliances Corp., 372 S.W.2d 41 (Mo. 1963).

All products: See the sweeping dictum in Beck v. Spindler, 256 Minn. 543, 99 N.W.2d 670 (1959).

Statutes applicable to all products: Ga. Code Ann. § 96-307; Va. Code Ann., 1960 Supp., § 8-654.3; Wyo. Stats., 1961 Cum. Supp., § 40A-813.

4. The following jurisdictions still reject the rule stated in this Section, even as to food:

Alabama. Birmingham Chero-Cola Bottling Co. v. Clark, 205 Ala. 678, 89 So. 64, 17 A.L.R. 667 (1921); Sterchi Bros. Stores v. Castleberry, 28 Ala. App. 281, 182 So. 471 (1937). Cases in the intermediate courts have accepted the strict liability, but apparently are not the present law. Dothan Chero-Cola Bottling Co. v. Weeks, 36 Ala. App. 639, 80 So. 734 (1953), disapproved, Birmingham Chero-Cola Bottling Co. v. Clark, 205 Ala. 678, 89 So. 64, 17 A.L.R. 667 (1921); Alabama Chero-Cola Bottling Co. v. Ezzell, 22 Ala. App. 210, 114 So. 278 (1927).

Arkansas. Drury v. Armour & Co., 140 Ark. 371, 216 S.W. 40 (1919); Nelson v. Armour Packing Co., 76 Ark. 352, 90 S.W. 288, 6 Ann. Cas. 237 (1905); Great A. & P. Tea Co. v. Gwilliams, 189 Ark. 1037, 76 S.W.2d 65 (1934).

Kentucky. Nehi Bottling Co. v. Thomas, 236 Ky. 684, 33 S.W.2d 701 (1930).

Maine. Pelletier v. Dupont, 124 Me. 269, 128 A. 186, 39 A.L.R. 972 (1925).

Massachusetts. Gearing v. Berkson, 223 Mass. 257, 111 N.E. 785, L.R.A.1916D, 1006 (1916); Newhall v. Ward Baking Co., 240 Mass. 434, 134 N.E. 625 (1922); Carlson v. Turner Centre System, 263 Mass. 339, 161 N.E. 245 (1928); Kennedy v. Brockelman Bros. 334 Mass. 225, 134 N.E.2d 747 (1956); Karger v. Armour & Co., 17 F. Supp. 484 (D. Mass. 1936).

New Hampshire. Howson v. Foster Beef Co., 87 N.H. 200, 177 A. 656 (1935); Hazelton v. First National Stores, 88 N.H. 409, 190 A. 280 (1937); Smith v. Salem Coca-Cola Bottling Co., 92 N.H. 97, 25 A.2d 125 (1942); Russell v. First National Stores, 96 N.H. 471, 79 A.2d 573 (1951).

North Carolina. Thomason v. Ballard & Ballard Co., 208 N.C. 1, 179 S.E. 30 (1935); Enloe v. Charlotte Coca-Cola Bottling Co., 208 N.C. 305, 180 S.E. 582 (1935); Caudle v. F. M. Bohannon Tobacco Co., 220 N.C. 105, 16 S.E.2d 680 (1941). See Prince v. Smith, 254 N.C. 768, 119 S.E.2d 923 (1961).

Rhode Island. Minutilla v. Providence Ice Cream Co., 50 R.I. 43, 144 A. 884, 63 A.L.R. 334 (1929); Lombardi v. California Packing Sales Corp., 83 R.I. 51, 112 A.2d 701 (1955).

South Dakota. Whitethorn v. Nash-Finch Co., 67 S.D. 465, 293 N. W. 859 (1940).

West Virginia. Burgess v. San-

itary Meat Market, 121 W. Va. 605, 5 S.E.2d 785 (1939).

Wisconsin. Prinsen v. Russon, 194 Wis. 142, 215 N.W. 905 (1927); Cohan v. Associated Fur Farms, 261 Wis. 584, 53 N.W.2d 788 (1952).

5. The rule stated is supported, as to other products for intimate bodily use, by the following cases:

Hair dye: Graham v. Bottenfield's, Inc., 176 Kan. 68, 269 P. 2d 413 (1954).

Soap: Krupar v. Proctor & Gamble Co., 113 N.E.2d 603 (Ohio App. 1953), reversed on other grounds, 160 Ohio St. 489, 52 Ohio Op. 363, 117 N.E.2d 7 (1954).

Detergent, coming in contact with hands: Worley v. Proctor & Gamble Mfg. Co., 241 Mo. App. 1114, 253 S.W.2d 532 (1952), express warranty also found; Hamon v. Digliani, 148 Conn. 710, 174 A.2d 294 (1961), same.

Permanent wave solution: Markovich v. McKesson & Robbins, Inc., 106 Ohio App. 265, 7 Ohio Op. 2d 10, 78 Ohio L. Abs. 111, 149 N.E.2d 181 (1958); Rogers v. Toni Home Permanent Co., 167 Ohio St. 244, 4 Ohio Op. 2d 291, 147 N.E.2d 612, 75 A.L.R.2d 109 (1958); Patterson v. George H. Wayer, Inc., 189 Kan. 501, 370 P.2d 116 (1962).

Clothing: Chapman v. Brown, 198 F. Supp. 78 (D. Hawaii 1961), affirmed, 304 F.2d 149 (C.A.9), hula skirt.

Cigarettes: Ross v. Philip Morris Co., (E.D. Mo. Oct. 22, 1959, No. 9494), modifying the opinion in 164 F. Supp. 683 (W.D. Mo. 1958); Pritchard v. Liggett & Myers Tobacco Co. 295 F.2d 292, 22 N.C.C.A.3d 421 (3 Cir. 1961).

Surgical pin for setting bone fractures: Bowles v. Zimmer Mfg. Co., 277 F.2d 868, 76 A.L.R.2d 120 (7 Cir. 1960), Michigan law.

Poliomyelitis vaccine: Gottsdanker v. Cutter Laboratories, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320, 79 A.L.R.2d 290 (1960).

Comment f. All of the foregoing cases imposing strict liability have involved defendants engaged in the business of selling the particular products. Most of the courts have applied the rule to retail sellers as well as manufacturers. Mississippi and Missouri apparently will refuse to apply it to retailers. See Kroger Grocery Co. v. Lewelling, 165 Miss. 71, 145 So. 726 (1933); Elmore v. Grenada Grocery Co., 189 Miss. 370, 197 So. 761 (1940); Conner v. Great A. & P. Tea Co., 25 F. Supp. 855 (W.D. Mo. 1939); McIntyre v. Kansas City Coca-Cola Bottling Co., 85 F. Supp. 708 (W.D. Mo. 1949), appeal dismissed, 184 F.2d 671 (C.A.8).

The wholesaler's strict liability was rejected in Elmore v. Grenada Grocery Co., 189 Miss. 370, 197 So. 761 (1940); De Gouveia v. H. D. Lee Merc. Co., 231 Mo. App. 447, 100 S.W.2d 336 (1936); and Bowman Biscuit Co. v. Hines, 151 Tex. 370, 251 S.W.2d 153 (1952). It was applied in Swengel v. F. & E. Wholesale Grocery Co., 147 Kan. 555, 77 P.2d 930, 4 N.C.C.A. N.S. 709 (1938); Nichols v. Nold, 174 Kan. 613, 258 P.2d 317, 38 A.L.R.2d 887 (1953); Graham v. Bottenfield's, Inc., 176 Kan. 68, 269 P.2d 413 (1954); Nelson v. West Coast Dairy Co., 5 Wash. 2d 284, 105 P.2d 76, 130 A.L.R. 606 (1940), and approved in dicta in Hoskins v. Jackson Grain Co., 63 So. 2d 514 (Fla. 1953), and Davis v. Radford, 233 N.C. 283, 63 S.E.2d 822, 24 A.L.R.2d 906 (1951).

See also cases under division, chapter, topic, title, and subtitle that includes section under examination.

Comment h. The strict liability was applied to containers in Canada Dry Bottling Co. v. Shaw 118 So. 2d 840 (Fla. App. 1960); Nichols v. Nold, 174 Kan. 613, 258 P.2d 317, 38 A.L.R.2d 887 (1953); Johnson v. Louisiana Coca-Cola Bottling Co., 63 So. 2d 459, 463 (La. App. 1953); Mahoney v. Shaker Square Beverages, Inc., 46 Ohio Op. 250, 64 Ohio L. Abs. 200, 102 N.E.2d 281 (C.P. 1951); Vallis v. Canada Dry Ginger Ale, Inc. 190 Cal. App. 2d 35, 11 Cal. Rptr. 823 (1961); Jones v. Burgermeister Brewing Corp., 198 Cal. App. 2d 198, 18 Cal. Rptr. 311 (1961).

Contra are Soter v. Griesedieck Western Brewery Co., 200 Okla. 302, 193 P.2d 575, 4 A.L.R.2d 458 (1948); McAlester Coca-Cola Bottling Co. v. Lynch, 280 P.2d 466 (Okla. 1955); Anheuser-Busch, Inc. v. Butler, 180 S.W.2d 996 (Tex. Civ. App. 1944); Latham v. Coca-Cola Bottling Co., 175 S.W. 2d 426 (Tex. Civ. App. 1943).

Comment k. Recovery was allowed to a customer in a beauty shop whose hair was treated with defendant's product, in Graham v. Bottenfield's, Inc., 176 Kan. 68, 269 P.2d 413 (1954); Patterson v. George H. Weyer, Inc., 189 Kan. 591, 370 P.2d 116 (1962), and to a housewife who contracted tularemia in cooking rabbits purchased by her husband, in Haut v. Kleene, 320 Ill. App. 273, 50 N.E. 2d 855 (1943). See also Thompson v. Reedman, 199 F. Supp. 120 (E.D. Pa. 1961), riding in automobile; Hinton v. Republic Aviation Corp., 180 F. Supp. 31 (S.D. N.Y. 1959), passenger in airplane; Middleton v. United Aircraft Corp., 204 F. Supp. 856 (S.D. N.Y. 1960), same; Ewing v. Lockheed Aircraft Corp., 202 F. Supp. 216 (D. Minn. 1962); Goldberg v. Kollsman Instrument Corp., 12 N.Y.2d 432, 191 N.E.2d 81 (1963); Siegel v. Braniff Airways, 204 F.Supp 861 (S.D. N.Y. 1960).

Members of the family of the final purchaser, consuming the product, recovered in Jacob E. Decker & Sons, Inc. v. Capps, 139 Tex. 609, 164 S.W.2d 828, 142 A.L.R. 1479 (1942); Griggs Canning Co. v. Josey, 139 Tex. 623, 164 S.W.2d 835, 142 A.L.R. 1424 (1942), answer conformed to, 165 S.W.2d 203 (Tex. Civ. App); Swengel v. F. & E. Wholesale Grocery Co., 147 Kan. 555, 77 P.2d 930, 4 N.C.C.A. N.S. 709 (1938); Nichols v. Nold, 174 Kan. 613, 258 P.2d 317, 38 A.L.R.2d 887 (1953); Swift & Co. v. Wells, 201 Va. 213, 110 S.E.2d 203 (1959); Blanton v. Cudahy Packing Co., 154 Fla. 872, 19 So. 2d 313 (1944); Welter v. Bowman Dairy Co., 318 Ill. App. 305, 47 N.E.2d 739 (1943); Davis v. Van Camp Packing Co., 189 Iowa 775, 176 N.W. 382, 17 A.L.R. 649 (1920); Greenberg v. Lorenz, 9 N.Y.2d 195, 213 N.Y.S.2d 39, 173 N.E.2d 773 (1961); Gottsdanker v. Cutter Laboratories, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320, 79 A.L.R.2d 290 (1960). See also Henningsen v. Bloomfield Motors, Inc., 32 N.J. 358, 161 A.2d 69, 75 A.L.R.2d 1 (1960), wife driving automobile; Thompson v. Reedman, 199 F. Supp. 120 (E.D. Pa. 1961), wife riding in automobile.

Employees of the final purchaser recovered in Mahoney v. Shaker Square Beverages, Inc., 46 Ohio Op. 250, 64 Ohio L. Abs. 200, 102 N.E.2d 281 (Com. Pl. 1951); Vallis v. Canada Dry Ginger Ale, Inc., 190 Cal. App. 2d 35, 11 Cal. Rptr. 823 (1961); Jones v Burgermeister Brewing Corp., 198 Cal. App.

Cit.—cited; fol.—followed; quot.—quoted; sup.—support.
A complete list of abbreviations faces page 1.

2d 198, 18 Cal. Rptr. 311 (1961); Simpson v. Eichenbrunner, 31 Misc. 2d 958, 217 N.Y.S.2d 678 (1961); Jabukowski v. Minnesota Mining & Mfg. Co., 80 N.J.Super. 184, 193 A.2d 275; Williams v. Union Carbide Corp., 17 App.Div. 2d 661, 230 N.Y.S.2d 476. See also Peterson v. Lamb Rubber Co., 54 Cal. 2d 339, 5 Cal. Rptr. 863, 353 P.2d 575 (1960), grinding wheel. In Revlon, Inc. v. Murdock, 103 Ga. App. 842, 120 S.E. 2d 912 (1961), the court refused to hold that a statute imposing strict liability to the consumer applied to the employee of a beauty shop who was injured while handling a bottle of nail polish.

Guests of the final purchaser recovered in Miller v. Louisiana Coca-Cola Bottling Co., 70 So. 2d 409 (La. App. 1954); Welch v. Schiebelhuth, 11 Misc. 2d 312, 169 N.Y.S.2d 309 (1957). See also Thompson v. Reedman, 199 F. Supp. 120 (E.D. Pa. 1961), wife riding in car. In Serrano v. Riverside Dinette Products Co., 222 N.Y.S.2d 537 (Sup. Ct. 1961), the court refused to extend the New York rule to a guest.

Donees of the final purchaser recovered in Coca-Cola Bottling Works v. Lyons, 145 Miss. 876, 111 So. 305 (1927); Klein v. Duchess Sandwich Co., 14 Cal. 2d 272, 93 P.2d 799 (1939); Nemela v. Coca-Cola Bottling Co., 104 S.W.2d 773 (Mo. App. 1937); Blarjeske v. Thompson's Restaurant Co., 325 Ill. App. 189, 59 N.E. 2d 320 (1945); Chapman v. Brown, 198 F. Supp. 78 (D. Hawaii, 1961), affirmed, 304 F.2d 149 (C.A.9), gratuitous bailee.

Caveat: Recovery was denied to non-consumers in Mull v. Colt Co., 31 F.R.D. 154 (S.D. N.Y. 1962), where a pedestrian was hit by an automobile; Jax Beer Co. v. Schaeffer, 173 S.W.2d 285 (Tex. Civ. App. 1943), employee of retailer; Loch v. Confair, 361 Pa. 158, 63 A.2d 24 (1949), shopper in self-service store; Hochgertel v. Canada Dry Corp., 409 Pa. 610, 187 A.2d 575 (1963), employee of purchaser; Rodriguez v. Shell's City, Inc., 141 So. 2d 590 (Fla. App. 1962), bystander injured when sanding kit disintegrated; Torpey v. Red Owl Stores, 129 F. Supp. 404 (D. Minn. 1955), affirmed, 228 F.2d 117 (8 Cir. 1956), friend offering assistance in sealing jar. The question was, however, left open in Courtois v. General Motors Corp., 37 N.J. 525, 182 A.2d 545 (1962). See also Chapman Chemical Co. v. Taylor, 215 Ark. 650, 222 S.W.2d 820 (1949), where the maker of a crop-dusting compound, dangerous because likely to drift, was held liable to an injured stranger, on the basis of abnormally dangerous activity.

Cross References to

1. **Digest System Key Numbers**
   Negligence ⇐27
   Torts ⇐1

2. **A.L.R. Annotation**
   Implied warranty, by other than packer, of fitness of goods sold in sealed cans. 142 A.L.R. 1434.
   Liability of one serving food for breach of implied warranty of fitness. 7 A.L.R.2d 1027.

See also cases under division, chapter, topic, title, and subtitle that includes section under examination.

Liability of manufacturer or seller for injury caused by food or food product sold. 77 A.L.R.2d 7.

Liability of manufacturer or seller for injury caused by beverage sold. 77 A.L.R.2d 215.

Infected or tainted condition of milk or other food, or contamination of water, and its causation of the sickness of the consumer, as inferable from such sickness. 130 A.L.R. 616.

Seller's or manufacturer's liability for injuries as affected by buyer's or user's allergy or unusual susceptibility to injury from article. 26 A.L.R.2d 958.

Privity of contract as essential to recovery in negligence action against manufacturer or seller of product alleged to have caused injury. 74 A.L.R.2d 1111.

Knowledge or actual negligence on part of seller which is not an element of criminal offense under penal statute relating to sale of unfit food or other commodity, as condition of civil action in tort in which violation of the statute is relied upon as negligence per se or evidence of negligence. 128 A.L.R. 464.

Res ipsa loquitur as applied to bursting of bottled beverages, food containers, etc. 4 A.L.R.2d 466.

Right of retailer sued by consumer for breach of implied warranty of wholesomeness or fitness of food or drink, to bring in as a party defendant the wholesaler or manufacturer from whom article was procured. 24 A.L.R.2d 913.

§ 402 B. Misrepresentation by Seller of Chattels to Consumer.

REPORTER'S NOTES

This Section has been added to the first Restatement. It is supported by the following decisions:

Labels on the goods themselves: Conestoga Cigar Co. v. Finke, 144 Pa. St. 159, 22 A. 868, 13 L.R.A. 438 (1891), tag on tobacco; Darks v. Scudders-Gale Grocer Co., 146 Mo. App. 246, 130 S.W. 430 (1910), opinion adopted on retransfer, 171 Mo. App. 37, 153 S.W. 1139, ginger extract; Graham v. John R. Watts & Son, 238 Ky. 96, 36 S.W.2d 859 (1931), seed; Simpson v. American Oil Co., 217 N.C. 542, 8 S.E.2d 813, 7 N.C.C.A. N.S. 774 (1940), insecticide; Free v. Sluss, 87 Cal. App. 2d Supp. 933, 197 P.2d 854 (1948), detergent; Davis v. Radford, 233 N.C. 283, 63 S.E.2d 822, 24 A.L.R.2d 906 (1951), dictum, salt substitute; Randall v. Goodrich-Gamble Co., 238 Minn. 10, 54 N.W.2d 769 (1952), dictum, liniment; Worley v. Procter & Gamble Mfg. Co., 241 Mo. App. 1114, 253 S.W.2d 532 (1952), washing powder; Hoskins v. Jackson Grain Co., 63 So. 2d 514 (Fla. 1953), watermelon seed; Lane v. C. A. Swanson & Sons, 130 Cal. App. 2d 210, 278 P.2d 723 (1955), "boned chicken"; Bonker v. Ingersoll Products Corp., 132 F. Supp. 5 (D. Mass. 1955), "boneless chicken fricassee"; Maecherlein v. Sealy Mattress Co., 145 Cal. App. 2d 275, 302 P.2d 331 (1956), mattress; plaintiff stabbed in her "gluteal prominence"; Wise v. Hayes, 58 Wash. 2d 106, 361 P.2d 171 (1961), insecticide.

Seller's advertising: Laclede Steel Co. v. Silas Mason Co., 67 F.

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A complete list of abbreviations faces page 1.

SECTION 11 - PREEMPTION RULINGS

2025880409

2025880409

Preemption

Adequacy of warning is a central issue in tobacco product liability suits. A ruling by the U.S. Court of Appeals for the Third Circuit holds that warnings on cigarette packs and in cigarette ads as prescribed by the Cigarette Labeling and Advertising Act of 1965 are adequate as a matter of law.

Following are:

- Preemption Ruling by the U.S. Court of Appeals for the Third Circuit.
- Petition for Rehearing with Suggestions for Rehearing En Banc.
- Denial of Rehearing and for Rehearing En Banc by the U.S. Court of Appeals for the Third Circuit.
- U.S. Court of Appeals for Sixth Circuit.
- U.S. Court of Appeals for First Circuit.
- Petition for Certiorari
- Preemption Questions and Answers

PREEMPTION RULING BY THE
U.S. COURT OF APPEALS
FOR THE THIRD CIRCUIT

417(F)
46

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 85-5073 and 85-5074

ANTONIO CIPOLLONE, individually and as Executor of the Estate of Rose D. Cipollone

v.

LIGGETT GROUP, INC., a Delaware Corporation; PHILIP MORRIS INCORPORATED, a Virginia Corporation and LOEWS CORPORATION, a Delaware Corporation and LOEW'S THEATRES, INC., a New York Corporation

Liggett Group, Inc., Appellant in 85-5073
Loew's Theatres, Inc., Appellant in 85-5074

On Appeal from the United States District Court
for the District of New Jersey - Newark
D.C. No. 83-2864

Argued February 13, 1986

Before: HUNTER, SLOVITER, *Circuit Judges*, and GILES,* *District Judge*

Opinion filed April 7, 1986

Paul M. Bator (Argued)
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Cambridge, Massachusetts 02138
Attorney for Appellants

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*Honorable James T. Giles, United States District Judge for the District of Eastern Pennsylvania, sitting by designation.

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OPINION OF THE COURT

HUNTER, *Circuit Judge*:

1. This case, before the court on the district court's certification pursuant to 28 U.S.C. § 1292(b) (1982), presents the question whether the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1331-1340 (1982) (the "Act"), preempts any or all of the state common law claims brought by appellee Antonio Cipollone and his wife Rose in the district court. Several of the claims in the Cipollones' complaint concern the alleged failure of the defendants, Liggett Group, Inc., Philip Morris Incorporated, Loews Corporation, Loew's Theatres Inc. ("Lorillard"), to provide an adequate warning of the dangers of the cigarettes that they manufactured and sold. Because these claims implicate the legislatively mandated warning provided in section 1333 of the Act, the answers of Liggett Group, Philip Morris, and Lorillard each included a defense based on the preemptive effect of the Act. The Cipollones responded by filing a motion to strike the preemption defenses. Lorillard, later joined by Philip Morris, then moved for judgment on the pleadings pursuant to Federal Rule Civil Procedure 12(c). Holding that the Act preempted none of the Cipollones' claims, the district court granted the Cipollones' motion to strike the defenses and denied the motion for judgment on the pleadings. *Cipollone v. Liggett Group, Inc.*, 593 F. Supp. 1146, 1171 (D.N.J. 1984). On January 21, 1984, this court granted appellants Lorillard and Liggett Group permission to appeal.[1] Because we disagree with the

1. Liggett Group petitioned for leave to appeal only from the portion of the district court's order granting the Cipollones' motion to strike defenses. *See* Joint Appendix at A205. Lorillard sought leave to appeal from the entire order, which included a denial of its motion for judgment on the pleadings. *See* Joint Appendix at A203.

district court's conclusion concerning the preemptive effect of the Act, we will reverse the district court's grant of the motion to strike and will remand the case for further proceedings.

I.

A. The Complaint

2. In their complaint, Rose and Antonio Cipollone alleged that Mrs. Cipollone developed lung cancer as a result of smoking cigarettes manufactured and sold by appellants. The complaint, which was originally filed on August 1, 1983, further averred that Mrs. Cipollone began smoking in 1942 and developed lung cancer as a result of her smoking. Mrs. Cipollone died in October 1984, but her husband has continued prosecuting this action, individually and as executor of his wife's estate. Mr. Cipollone is therefore the sole appellee in this case.

3. As observed by the district court, the fourteen-count complaint sets forth claims based on strict liability (Counts 2, 3, and 9), negligence (Counts 4 and 5), breach of warranty (Count 7), and intentional tort (Counts 6 and 8). The Cipollones claimed that the defendants' cigarettes were unsafe and defective (Count 2) and that defendants are subject to liability for their failure to warn of the hazards of cigarette smoking on the basis of negligence (Count 4) or strict liability (Count 3). In addition, the Cipollones asserted, defendants negligently (Count 5) or intentionally (Count 6) advertised their products in a manner that neutralized the warnings actually provided, warnings made meaningless by the addiction created by

Nevertheless, both appellants made clear in their reply brief and at oral argument that they did not challenge the district court's denial of Lorillard's motion for judgment on the pleadings. *See* Reply Brief of Appellants at 3; Transcript of Oral Argument at 7, 18. We will therefore consider only the district court's grant of the motion to strike.

cigarettes (Count 9). Finally, the complaint stated that the defendants ignored, failed to act upon, and conspired to deprive the public of medical and scientific data reflecting the dangers associated with cigarettes (Count 8).[2]

B. The Federal Cigarette and Advertising Labeling Act

4. The Federal Cigarette Labeling and Advertising Act, originally enacted in 1965, was a response to a growing awareness among members of federal as well as state government that cigarette smoking posed a significant health threat to Americans. The original Act required the following warning label on cigarette packages: "Caution: Cigarette Smoking May Be Hazardous to Your Health." 15 U.S.C. § 1333 (1970). Congress changed this warning, by amendment to the Act in 1969, to the following: "Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health." 15 U.S.C. § 1333 (1976).[3] The Act, as

---

2. Counts 1 and 10 through 14 are not pertinent to this appeal.

3. In 1984, Congress replaced this warning with rotational warnings providing:

> SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.
>
> SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.
>
> SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result In Fetal Injury, Premature Birth, And Low Birth Weight.
>
> SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

15 U.S.C. § 1333(a)(1) (Supp. II 1984). The 1984 warning, however, has limited relevance here because the complaint contains no allegation that Mrs. Cipollone smoked cigarettes manufactured and sold by any defendant after 1981.

amended in 1970, expressly stated the policy behind the required warning:

> It is the policy of the Congress, and the purpose of this chapter, to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby--
>
> (1) the public may be adequately informed that cigarette smoking may be hazardous to health by inclusion of a warning to that effect on each package of cigarettes; and
>
> (2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

15 U.S.C. § 1331 (1982).[4]

5. The Act also contains a preemption provision, which provides that

> (a) No statement relating to smoking and health, other than the statement required by section 1333 of this title, shall be required on any cigarette package.

---

4. Congress amended paragraph one of section 1331 in 1984 by adding a reference to warning notices in cigarette advertisements. Paragraph one now provides: "(1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes . . . ." 15 U.S.C. § 1331(1) (Supp. II 1984).

> (b) No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.

15 U.S.C. § 1334 (1982). Confronted with this provision, the district court did not question that the Act prohibits state legislatures from requiring a warning on cigarette packages that alters that provided in section 1333. Nevertheless, after a comprehensive analysis of the Act, the court concluded that section 1334 does not preempt state common law claims such as those that the Cipollones have asserted.

II.

A. Preemption Principles

6. The United States Supreme Court has identified several principles for ascertaining congressional intent to preempt state authority. To begin, Congress may preempt state law by express statement. *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). Without the aid of express language, a court may find intent to preempt in two general ways. *Silkwood v. Kerr-McGee Corp.*, 104 S.Ct. 615, 621 (1984). First, a court may determine that Congress intended "to occupy a field" in a given area

> because '[t]he scheme of federal regulation may be so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it,' because 'the Act of Congress may touch a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject,' or because 'the object sought to be obtained by the federal law

and the character of obligations imposed by it may reveal the same purpose.'

Fidelity Federal Savings & Loan Association v. De la Cuesta, 458 U.S. 141, 153 (1982) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Second, in those instances where Congress has not wholly superceded state regulation in a specific area, state law is preempted "to the extent that it actually conflicts with federal law." *Pacific Gas & Electric Co. v. Energy Resources Conservation & Development Commission*, 461 U.S. 190, 204 (1982). The Court has stated that such conflict arises when "compliance with both federal and state regulations is a physical impossibility," *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963), or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). Finally, in applying these principles, a court must be mindful of the overriding presumption that "Congress did not intend to displace state law." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981); *see also Rice*, 331 U.S. at 230.

B. Express Preemption

7. In applying these principles to the statutory scheme at issue here, we first express our agreement with the district court's conclusion that section 1334 does not provide for express preemption of the Cipollones' state common law claims. *See Cipollone*, 593 F. Supp. at 1154-55; *accord Roysdon v. R.J. Reynolds Tobacco Co.*, No. 3-84-606, slip op. at 2 (E.D. Tenn. Dec. 18, 1985); *Roysdon v. R.J. Reynolds*, No. 3-84-606, slip. op. at 2 (E.D. Tenn. Dec. 11, 1985). Because we are constrained by the presumption against preemption, we cannot say that the language of section 1334 clearly encompasses state common law.

We find support for this determination in Congress's failure to include state common law explicitly within section 1334, as it has in numerous other statutes.[5] Indeed, in the absence of a preemption provision encompassing state common law, the Supreme Court has relied generally on principles of implied preemption in evaluating whether a statutory scheme preempts state common law. *See, e.g., Silkwood v. Kerr-McGee Corp.*, 104 S.Ct. 615 (1984); *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311 (1981). Accordingly, we turn to examining whether congressional intent to preempt the Cipollones' claims may be inferred under the two general principles of implied preemption.

C. Implied Preemption

8. In pressing their implied preemption arguments in this appeal, each side relies extensively on the legislative history of the Act. As is often the case with legislative history, both sides have succeeded in gleaning passages that bolster their contrary positions. Although we find the legislative history to the Act informative, no materials have come to our attention that we deem wholly dispositive of the issue before us.

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5. Examples of statutes that include a preemption provision explicitly encompassing state common law include 12 U.S.C. §§ 1715z-17(d), 1715z-18(e) (Supp. II 1984) (Domestic Housing and International Recovery and Financial Stability Act); 17 U.S.C. § 301(a) (Copyright Act of 1976); and 29 U.S.C. § 1144(a), (c)(1) (1982) (Employee Retirement Income Security Act of 1974).

It should be noted that just as Congress could have included a reference to preemption of state common law in section 1334, it also could have included a "savings clause" explicitly preserving the continued vitality of state common law, such as that in the Occupational Safety and Health Act of 1970, 29 U.S.C. § 653(b)(4) (1982). Thus, lack of reference to preemption of state common law in section 1334 has significance only because of the presumption against preemption.

Even more important, we find the language of the statute itself a sufficiently clear expression of congressional intent without resort to the Act's legislative history. *See Blum v. Stenson*, 104 S.Ct. 1541, 1548 (1984); *Piper v. Chris-Craft Industries, Inc.*, 430 U.S. 1, 26 (1977).

9. Under the principles of implied preemption, we must first determine whether Congress intended "to occupy the field" relating to cigarettes and health to the exclusion of state law product liability actions such as the Cipollones. Our examination of the Act leads us to agree with the district court's statements that "Congress . . . intended to occupy *a* field" and "indicated this intent as clearly as it knew how." *Cipollone*, 593 F.Supp. at 1164 (emphasis in original). Not only did Congress use sweeping language in describing the preemptive effect of the Act in section 1334, but it expressed its desire in section 1331 to establish "a comprehensive Federal program" in order to avoid "diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health." *See Palmer v. Liggett & Myers Tobacco, Inc.*, No. 83-2445-MA (D. Mass. Feb. 1, 1984) (Congress has preempted field with respect to cigarette labeling).

10. In determining the scope of this field, we observe that the Cipollones' tort action concerns rights and remedies traditionally defined solely by state law. We therefore must adopt a restrained view in evaluating whether Congress intended to supercede entirely private rights of action such as those at issue here. *See Rice*, 331 U.S. at 230; *Cipollone*, 593 F. Supp. at 1165-66; *see also Silkwood*, 104 S.Ct. at 623-24; *Florida Avocado Growers*, 373 U.S. at 143-44. In light of this constraint, we cannot say that the scheme created by the Act is "so pervasive" or the federal interest involved "so dominant" as to eradicate

all of the Cipollones' claims. Nor are we persuaded that the object of the Act and the character of obligations imposed by it reveal a purpose to exert exclusive control over every aspect of the relationship between cigarettes and health. *See Banzhaf v. F.C.C.*, 405 F.2d 1082, 1089-91 (D.C. Cir. 1968), *cert. denied*, 396 U.S. 842 (1969); *see also Southern Railway Co. v. Railroad Commission of Indiana*, 236 U.S. 439, 446-48 (1915). Thus, we look to the extent to which the Cipollones' state law claims "actually conflict" with the Act to ascertain whether they are preempted.

11. The test enunciated by this court for addressing a potential conflict between state and federal law requires us "to examine first the purposes of the federal law and second the effect of the operation of the state law on these purposes." *Finberg v. Sullivan*, 634 F.2d 50, 63 (3d Cir. 1980) (in banc) (citing *Perez v. Campbell*, 402 U.S. 637 (1971)). As mentioned above, Congress has provided us with an explicit statement of the Act's purposes in section 1331. That statement reveals that the Act represents a carefully drawn balance between the purposes of warning the public of the hazards of cigarette smoking and protecting the interests of national economy. *See Banzhaf*, 405 F.2d at 1090. Moreover, the preemption provision of section 1334, read together with section 1331, makes clear Congress's determination that this balance would be upset by either a requirement of a warning other than that prescribed in section 1333 or a requirement or prohibition based on smoking and health "with respect to the advertising or promotion" of cigarettes. *See* 15 U.S.C. § 1334.

12. Having identified the purposes of the Act, we now must evaluate the effect of the operation of state common law claims on these purposes. In so doing, we accept the appellants' assertion that the duties imposed through state common law damage actions

have the effect of requirements that are capable of creating "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *See Hines*, 312 U.S. at 67; *see also Dawson v. Chrysler Corp.*, 630 F.2d 950, 962 (3d Cir. 1980) (liability under common law has the effect of imposing requirements), *cert. denied*, 450 U.S. 959 (1981). As the appellants point out, several Supreme Court opinions reflect recognition of the regulatory effect of state law damage claims and their potential for frustrating congressional objectives. *See, e.g., Fidelity*, 458 U.S. at 156-59; *Chicago & North Western Transportation Co.*, 450 U.S at 324-25; *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 247 (1959).[6] Applying this principle, we conclude that claims relating to smoking and health that result in liability for noncompliance with warning, advertisement, and promotion obligations other than those prescribed in the Act have the effect of tipping the Act's balance of purposes and therefore actually conflict with the Act.

13. Based on the foregoing, we hold that the Act preempts those state law damage actions relating to smoking and health that challenge either the adequacy of the warning on cigarette packages[7] or the propriety of a party's actions with respect to the advertising and

6. The district court noted that *Garmon* involved claims based on state statutes, rather than state common law. This distinction does not undermine the significance of *Garmon*. As the appellants argue, the central inquiry should be whether a state statute or common law rule providing for civil liability is regulatory in its effect. The *Garmon* Court ruled that a claim for compensation has a regulatory nature and therefore may be preempted by a federal regulatory scheme. *Garmon*, 359 U.S. at 247-48.

7. *Accord Roysdon*, slip op. at 3-4 (Dec. 18, 1985); *Roysdon*, slip op. at 3 (Dec. 11, 1985).

promotion of cigarettes. We further hold that where the success of a state law damage claim necessarily depends on the assertion that a party bore the duty to provide a warning to consumers in addition to the warning Congress has required on cigarette packages, such claims are preempted as conflicting with the Act.

14. As appellant's counsel conceded at oral argument, it is not necessary at this stage of the litigation for us to identify which of the Cipollones' claims are preempted by the Act. Under 28 U.S.C. § 1292(b), we are obliged to address the order that was certified rather than the controlling question of law framed by the district court.[8] *Johnson v. Alldredge*, 488 F.2d 820, 822-23 (3d Cir. 1973), *cert. denied*, 419 U.S. 882 (1974); *see, e.g., Murphy v. Heppenstall Co.*, 635 F.2d 233, 235 n.1 (3d Cir. 1980), *cert. denied*, 454 U.S. 1142 (1982). The district court's statement of the controlling issue appears to call for a definitive ruling on each of the Cipollones' claims. Nevertheless, we need only decide whether the district court's ruling striking appellants' preemption defenses should be

8. Section 1292(b) provides:

> When a district judge, in making in a civil action an order not otherwise appealable under this section, shall be of the opinion that such order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation, he shall so state in writing in such order. The Court of Appeals which would have jurisdiction of an appeal of such action may thereupon, in its discretion, permit an appeal to be taken from such order, if application is made to it within ten days after the entry of the order: Provided, however, That application for an appeal hereunder shall not stay proceedings in the district court unless the district judge or the Court of Appeals or a judge thereof shall so order.

affirmed or reversed.[9] Two principles counsel us to take such an approach. First, a court should avoid a holding of preemption that is premised on a merely potential conflict between state and federal law. *See Rice*, 438 U.S. at 659. In addition, a court should not grant a motion to strike a defense unless the insufficiency of the defense is "clearly apparent." *See May v. Department Stores Co. v. First Hartford Corp.*, 435 F. Supp. 849, 855 (D. Conn. 1977); Wright & Miller, Federal Practice and Procedure § 1381, at 802 (1969). The underpinning of this principle rests on a concern that a court should restrain from evaluating the merits of a defense where, as here, the factual background for a case is largely undeveloped. *See* id. at 800-02.

15. Mindful of both of these principles, we deem it appropriate to reverse the order of the district court and remand the case for further development of the claims and theories of the parties. The district court will then be in a position to make informed and definitive rulings on which claims then in contention are preempted.

III.

16. For the foregoing reasons, we will reverse the order of the district court to the extent that it granted the Cipollones' motion to strike appellants' preemption defenses. We will also remand the case for further proceedings consistent with this opinion.

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9. In *Johnson*, we stated that section 1292(b) "does not speak of the court of appeals deciding a question certified by the district court. . . . Since under the clear terms of section 1292(b), we are called upon not to answer the question certified but to decide an appeal, we do not find ourselves bound by the District Judge's statement of the issue." 488 F.2d at 822-23.

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PETITION FOR REHEARING
W/SUGGESTIONS FOR REHEARING
EN BANC

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UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Docket Nos. 85-5073 and 85-5074

ANTONIO CIPOLLONE, individually and as Executor of the Estate of Rose D. Cipollone,

Plaintiff-Petitioner

vs.

LIGGETT GROUP INC., a Delaware Corporation, PHILIP MORRIS INCORPORATED, a Virginia Corporation, and LOEW'S THEATRES, INC., a New York Corporation,

Defendants-Appellants.

On Appeal from the United States District Court for the District of New Jersey - Newark, DC No. 83-2864
Sat Below: Hon. H. Lee Sarokin, U.S.D.J.

PETITION FOR REHEARING WITH SUGGESTION FOR REHEARING EN BANC

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES

STATUTES CITED

OTHER AUTHORITIES CITED

TABLE OF AUTHORITIES

REQUIRED STATEMENT FOR REHEARING EN BANC

We express a belief, based on a reasoned and studied professional judgment, that the panel decision is contrary to and inconsistent with other decisions of the Third Circuit and the United States Supreme Court, specifically Dawson v. Chrysler Corp., 630 F.2d 950 (3rd Cir. 1980), cert. denied, 450 U.S. 959 (1981) and Silkwood v. Kerr-McGee, 464 U.S. 238 (1984). Consideration by the full court is necessary to secure and maintain uniformity of decisions in this court. In addition, the panel failed to apply the required principles of legislative interpretation as set forth in Lorillard v. Pons, 434 U.S. 575 (1978). The exceptional importance of the issue on appeal is apparent: should traditional state tort law causes of action intended to compensate injured citizens be abrogated in the absence of an explicit congressional statement to do so or a substantial conflict between the Federal Cigarette Labeling and Advertising Act ("Act") and state law?

STATEMENT OF THE CASE

This was an appeal by defendants, cigarette manufacturers, from an order of the United States District Court for the District of New Jersey which granted plaintiff's motion to strike defendants' defense that plaintiff's claims were preempted by the Act, 15 U.S.C. §1331-1340 (1982). The appeal was argued on February 13, 1986, and on April 7, 1986, the panel issued its opinion reversing the order of the district court and remanding the case for further determination of which of plaintiff's claims were preempted. Contending that the opinion is flawed, appellees now seek rehearing en banc.

INTRODUCTION

Rose Cipollone smoked cigarettes from 1942 until 1982 when her right lung was removed as a result of cancer. She did not believe, even after the federally mandated warnings in 1966, that smoking was harmful to her health. The warnings did not convey to her the full extent of the dangers of cigarette smoking. Mrs. Cipollone did not want to believe her cigarette smoking was harmful. This desire was fed by the constant barrage of cigarette advertising designed to assuage her fears and which inferred that she would be "safe" if she smoked a lower tar and nicotine cigarette. Mrs. Cipollone, in fact, switched to lower tar and nicotine cigarettes.

Mrs. Cipollone claims are premised primarily on the absence of warnings prior to 1966, on her assertion that after 1966 the defendants failed to adequately convey to her the true extent of the dangers of smoking and that the warning required by the Act was undermined, if not neutralized by the advertising, promotional, and public relations activities of the tobacco companies.

On April 7, 1986, the panel issued a sweeping decision which preempts virtually all of plaintiff's post 1966 claims. It held that the Act

> preempts those state law damage actions relating to smoking and health that challenge either the adequacy of the warning on cigarette packages or the propriety of a party's actions with respect to the advertising and promotion of cigarettes [and any] state law damage claim [which] necessarily depends on the assertion that a party bore the duty to provide a warning to consumers in addition to the warning Congress has required. (Slip. op. at 12-13).

Although the panel remanded the case to the district court to decide which claims are preempted, its holding must be considered so broad as to sound the death knell to most of Mrs. Cipollone's post-1966 claims.

The decision provides the cigarette industry with a license to kill. Although on its face this may appear an emotional exaggeration, the following "factual" contentions illustrate the searing truth of that statement: (1) by 1966 the tobacco companies, through internal scientific research and other sources, had irrefutable proof that cigarette smoking caused lung cancer, heart disease, emphysema, and was physiologically addictive; (2) since 1966 they have intentionally withheld this information from the public for fear of lost profits; (3) since 1966 they have employed extremely effective advertising and promotional campaigns to assuage smokers' fears and to undermine the federally-mandated warnings; (4) since 1966 millions of Americans have died of lung cancer and other diseases caused by cigarette smoking; and (5) since 1966 millions of Americans have been unable to stop smoking because of its addictive nature.

This court has provided total immunity to the cigarette manufacturers for these intentional acts of wrongdoing and has eliminated the common law tort remedies of people injured and killed by cigarette smoking. A more exceptional and far reaching edict is unimaginable. Immunizing the defendants for such activities conflicts with the primary purpose of the Act--to adequately warn the public of the health hazards of cigarette smoking. Armed with this immunity defendants have no

incentive to disseminate more complete or newly discovered information about the adverse health consequences of cigarette smoking.

The Supreme Court in Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 104 S.Ct. 615, 621 (1984), found that a Tenth Circuit decision on a substantially similar issue was reviewable by writ of certiorari because of its importance, stating "it affects both the state's traditional authority to provide tort remedies to its citizens and the federal government's desire to maintain exclusive regulatory authority." The same interest is at stake here but this court's opinion is in direct contradiction to the holding in Silkwood. Its decision is also a misapplication of the law of preemption set forth in Silkwood and earlier Supreme Court opinions.

The panel's "conclusions" lack any factual analysis and are based upon nothing more than a superficial examination of the Act's language. Although this court's reasoning is far from clear, the holding appears grounded on the assertion that common law tort liability would have a "regulatory effect" and thus conflicts with the purposes and objectives of the Act. A determination that plaintiff's claims are preempted because they conflict with the Act requires more than a cursory examination of the Act's statement of purpose. It requires a comprehensive analysis of the purposes of the Act, congressional intent in that regard, and close scrutiny of what, if any, conflict exists and the effect of that conflict on the Act's purposes. If this analysis had been applied, there would have been an affirmation of the district court's order. The panel's decision is also incorrect because of its

failure to apply the principles of legislative construction as set forth in Lorillard v. Pons, 434 U.S. 573 (1978).

The opinion is even more remarkable in light of its acknowledgement of long established principles that the court "must adopt a restrained view in evaluating whether Congress intended to supercede entirely private rights of action" (Slip op. at 10) and that "a court must be mindful of the overriding presumption that "congress did not intend to displace state law" (Slip op. at 8). Despite the panel's recognition of these principles it disregarded them.

LEGAL ARGUMENT

THIS COURT INCORRECTLY APPLIED THE LAW OF PREEMPTION UNDER A CONFLICT ANALYSIS.

The Supreme Court, in carefully guarding the "federal-state" balance, has imposed a high standard for preemption of state authority: "federal regulation of a field of commerce should not be deemed preemptive of state regulatory power in the absence of persuasive reasons, either that the nature of the regulated subject matter permits no other conclusion or that the Congress has unmistakenly so ordained." Florida Lime and Avocado Growers v. Paul, 373 U.S. 132, 142 (1963). A "presumption" against preemption is mandated by concerns of federalism. Maryland v. Louisiana, 451 U.S. 725, 746 (1981); City of Milwaukee v. Illinois, 451 U.S. 304, 316 (1981).

This court recognized that the Act does not "expressly" preempt any common law claims (Slip op. at 8). It also determined that Congress

did not intend to "exert exclusive control over every aspect of the relationship between cigarettes and health." (Slip. op. at 11). The sole basis for its holding was its assertion that successful state tort claims based on inadequate warnings or advertising practices are "requirements" and are therefore preempted because they would conflict with the Act's purpose. This assertion is unsupported in fact, in law or by congressional intent.[1]

Because of the limitations of Fed. R. App. P. 40(b) it is impossible to provide a full exposition of the Act's legislative history. A review of that history, however, reveals that Congress did not intend to preempt common law claims, but rather proceeded under an assumption that common law tort rights would continue to exist after passage of the Act.[2]

Despite the panel's claim that Congress' 1984 reenactment of the

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1. Although this Court made reference in its opinion to a review of the legislative history, it entered into no discussion of its content nor did it address the "absence" of any statement of congressional intent to preempt common law claims or the undisputed testimony by congressman who assumed common law claims would continue.

2. See e.g., statement of Rep. Pascell who stated during the hearings that this law "could [not] be considered a legal or factual bar to the plaintiff user," that, in fact the law would "raise the presumption that every company that makes and distributes this product does so with knowledge [which fact] would redound to the benefit of a plaintiff bringing an injury suit. 111 Cong. Rec. 16,543 (July 13, 1965), Counsel to the United States Department of Health, noted that "products liability. . .is a private matter. . . not regulated by the bill." Cigarette Labeling and Advertising, Hearings on H.R. 3014 Before the House Committee on Interstate and Foreign Commerce, 89th Cong., 1st Sess. 176 (1965); Rep. Watson stated "nowhere in the Act of 1965 does it preclude an individual or prevent an individual from pursuing common-law liability against a tobacco company." Cigarette Labeling and Advertising, Hearings on H.R. 643, Before the House Committee on Interstate and Foreign Commerce, 91st Cong., 1st Sess. 554 and 577-81 (1969).

Act was of "limited relevance" (slip. op. at 5) that action is, in fact, presumptive of Congress' intent that the Act did not preempt any tort liability claims. "Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it reenacts a statute without change." Lorillard v. Pons, 434 U.S. 573, 581 (1978). Lindahl v. Office Personnel Mgmt., 105 S.Ct. 1620, 1629 (1985); Albermarle Paper Co. v. Moody, 422 U.S. 405, 414 n.8 (1975); National Labor Relations Bd. v. Gullett Gin Co., 340 U.S. 361, 366 (1951); Helvering v. R.J. Reynolds Tobacco Co., 306 U.S. 110, 114-15 (1939); In re Tiffany, 252 U.S. 140, 146-47 (1920); McDowell v. Avtex Fibers, 740 F.2d 214, 216 (3d Cir. 1984); 2A C. Sands, Sutherland on Statutory Construction §49.09 and cases cited (4th ed. 1973). The reenactment occurred on October 12, 1984. The only judicial interpretation regarding the defendants' assertion that the Act preempts tort liability was Judge Sarokin's decision of September 20, 1984. A fortiori, by not amending §1334 to specifically preempt common law tort liability Congressional intent is clear--State tort liability claims are not preempted.

Further evidence of Congress' intent that tort claims were to be uneffected by the Act is found in the Comprehensive Smokeless Tobacco Health Education Act of 1986, P.L. 99-252 enacted on February 27, 1986. That Act, modeled after the Cigarette Labeling Act, has the same legislative purpose and ALMOST the identical preemption provision. The significant difference in the preemption section of the Smokeless Tobacco Act is:

> (c) Effect on Liability Law.-Nothing in this Act shall relieve any person from liability at common law or under State statutory law to any other person.

Why did Congress find it necessary to include a savings clause in the Smokeless Tobacco Act and not in the Act in question? The answer is simple. When Congress reexamined and reenacted the Act in October 1984 and August 1985, without amending the preemption provision, the only judicial interpretation of its impact on tort liability cases was Judge Sarokin's. However, at the time the Smokeless Tobacco Act was enacted Judge Hull's decision in Roysdon v. R.J. Reynolds, 623 F. Supp. 1189 (E.D. Tenn., 1985), which came to the opposite conclusion on the preemption question, had been issued. Congress, faced with these conflicting interpretations, felt it necessary to affirm the correctness of Judge Sarokin's decision and did so by including subsection (c).

Subsection (c) also makes it manifestly clear that imposition of tort liability does not act as an obstacle to the accomplishment of the purpose of the Cigarette Labeling Act. The purposes of the Cigarette Labeling Act and the Smokeless Tobacco Act are identical. Since Congress determined that tort recovery based upon inadequate warnings in smokeless tobacco cases would not conflict with the accomplishment of that act, it is obvious that this court's opposite conclusion in cigarette cases is in error.

Since there was no express preemption and since there was no evidence of congressional intent to displace state common law claims this court could preempt the Cipollone's claims only "to the extent [they]

conflict with the Federal law, that is, when it is impossible to comply with both state and Federal law, . . ., or when state law stands as an obstacle to the accomplishment of the full purposes and objectives of Congress." Silkwood, supra, 104 S. Ct. at 621 (1984); Pacific Gas & Elec. Co. v. State Energy Resources Cons. & Dev. Comm., 461 U.S. 190, 204 (1983). In determining whether state and federal law "conflict", the United States Supreme Court considers the structure of the regulations involved, the extent of congressional superintendence of the field, the comprehensiveness and complexity of the federal scheme, the federal interest in the area, congressional intent, and the way in which state law would conflict with the above. See, e.g., San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236 (1959); Hines v. Davidowitz, 312 U.S. 52, 66 (1941); Fidelity Federal Savings & Loan Ass'n v. de la Cuesta, 458 U.S. 141 (1982); Silkwood v. Kerr McGee, supra.

The purposes of the Act were: (1) to adequately inform the public that cigarette smoking may be hazardous to health by inclusion of a warning on each package of cigarettes and in advertisements; and (2) insofar as consistent with the primary purpose of the Act, to provide a uniform label to protect commerce and the national economy.[3] 15 U.S.C. §1331 (1982). As to the first purpose, it cannot be logically argued that imposition of tort liability would impede the goal of adequately informing the public of dangers of smoking. See, supra. at 3. As to

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3. See, Cigarette Labeling and Advertising: Hearings on S. 559 and S. 547 Before the Senate Committee on Commerce, 89th Cong., 1st Sess. 39-40 (1965) (statement of Sen. Magnuson).

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the second purpose, it is also illogical to argue that state tort liability would "require" a different warning label in place of the one mandated by Congress.[4]

Defendants' "duty" under tort law is to provide adequate and accurate information about the health consequences of smoking by some means. Imposition of tort liability may create some "tension" by acting as an impetus for defendants to provide such information (e.g. by package inserts, as used by the pharmaceutical industry, or by public service advertising). It may also act as an incentive for defendants to be more cautious or accurate in the representations they make to the public in their advertisements.

The Act leaves defendants free to provide additional information regarding the health hazards of their products. Imposition of tort liability would do no more. Indeed, cigarette manufacturers currently supplement the mandated health warnings by use of paid advertisements which suggest that no causal relationship has been established between cigarette smoking and disease. It is incomprehensible that Congress intended that the tobacco companies be permitted to convince the public

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4. In fact, it is impossible under the circumstances in this case for plaintiffs' common law action to conflict with the purposes of the Act. Effective October 12, 1985, new warning labels were required on packages of cigarettes, different from the warnings Mrs. Cipollone was given from 1968 through 1982. Therefore, the jury in this case will pass upon the adequacy of federally mandated warnings abandoned by Congress because they were inadequate. 15 U.S.C. §1333 (West. Supp. 1988). It is apparent that if the jury finds these obsolete warnings inadequate, such a determination would have no effect on defendants' prospective compliance with the Act. Since it is not possible to regulate retrospectively, there can be no "regulatory effect" arising from a plaintiffs' verdict in this case and no resulting conflict.

of untruths and yet intended to preclude tort liability which might motivate them to tell the truth about cigarette smoking and disease. As the Supreme Court has observed in other contexts, federal courts should not "impute to Congress a purpose to paralyze with one hand what it sought to promote with the other." American Textile Mfrs. Inst. v. Donovan, 452 U.S. 490, 513 (1981).

The purpose of tort liability is "compensation" not regulation. O'Brien v. Muskin Corp., 94 N.J. 169, 179 (1983); Beshada v. Johns-Manville Products Corp., 90 N.J. 191, 208-06, 209 (1982). See also, People Express Airlines v. Consolidated Rail Corp., 100 N.J. 246, 255 (1985) (compensation is the "overarching" purpose of tort law). The Act does not provide for a means to compensate victims of cigarette use. The preemption of state tort liability would eliminate any method for compensation for injuries arising from the tortious conduct of cigarette manufacturers. As the Supreme Court stated in Silkwood, supra: "[i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." 104 S.Ct. at 623.

In Silkwood, the Supreme Court rejected the argument that tort claims premised on inadequate safety would have a regulatory effect and would therefore conflict with congress' purpose of regulating the entire field of nuclear safety. Silkwood involved an area of unquestionable national concern, atomic energy, where Congress had expressly stated its intent to preclude "dual regulation" of radiation hazards and in which the Court had previously held that the federal government had occupied the entire field of nuclear safety concerns. 104 S. Ct. at 626.

Even if we assume that different verdicts in different jurisdictions regarding the adequacy of the information supplied by defendants to their consumers creates "tension", such "tension" has been solidly rejected as a basis for preemption. The Supreme Court stated that the existence of a "tension between the conclusion that safety regulation is the exclusive concern of the federal law and the conclusion that a state may nevertheless award damages based on its own liability" is not enough to find preemption in the absence of an explicit statement of congressional intent to the contrary. 104 S. Ct. at 623. Moreover, the Court stated that in the absence of an express statement of Congressional intent, it is "defendant's burden to show that Congress intended to preclude such awards." Id. This Court improperly shifted the burden in holding in favor of abrogation of state tort rights.

The basis for the Court's holding in Silkwood is not dissimilar to this court's holding in Dawson v. Chrysler Corp., 630 F.2d 950, 962 (3d Cir. 1980), cert. denied, 450 U.S. 959 (1981). In that case this court disapproved of the fact that "[i]ndividual juries applying varying laws in different jurisdictions [may]. . .impose on automobile manufacturers conflicting requirements" but nonetheless, noted that congress "is the body best suited to evaluate and, if appropriate, to change that system," and if Congress chose not to displace common law it could not and would not act in its place. Id. at 963.

The Supreme Court has consistently upheld the viability of state statutes providing higher or different standards than those mandated under federal law. See, Exxon Corp. v. Governor of Maryland, 437 U.S. 117, 132 (1978) (Maryland statute which had an "anticompetitive effect"

held not preempted by federal act the purpose of which was to protect competition); Florida Lime & Avocado Growers v. Paul, supra, 373 U.S. 132 (state statute which gauged the maturity of avocados by a higher standard held not preempted by federal regulatory standards because no "physical impossibility" of dual compliance was presented since state growers could adjust their harvesting plans to meet both the federal and state standards.); Cloverleaf Butter Co. v. Patterson, 315 U.S. 148 (1942) (In the absence of an express contrary command of Congress, state may confiscate or exclude from market processed butter not complying with a standard demanded by a state for its consumers notwithstanding compliance with all federal processing standards). See also, Reid v. Colorado, 187 U.S. 137 (1902); Savage v. Jones, 225 U.S. 501 (1911).

More importantly, products liability actions based on failure to warn have consistently been permitted in the face of claims of preemption based on conflict with less inclusive federal regulations and standards. Many of these federal statutes have purposes identical to those of the Act: avoidance of diverse labeling requirements to protect the national economy, and provision of adequate warnings to the public. For example, the Food and Drug Administration regulates warnings on oral contraceptives with the express purpose of "fully" informing the public of the benefits and risks involved in use of the drugs and for the purpose of providing "precise and nationally uniform labeling." See 43 Fed. Reg. 4220-22 (1978); 21 C.F.R. §301.501(a). Compliance with federally mandated labeling requirements has never immunized the manufacturer from liability based on the inadequacy of the warning. See e.g., Skill

v. Martinez, 91 F.R.D. 498, 508 (D.N.J. 1981), aff'd, 677 F.2d 368 (3rd Cir. 1982); Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 652, 658 (1st Cir. 1981). In Feldman v. Lederle Laboratories, 97 N.J. 429 (1984), the New Jersey Supreme Court held that an action against a manufacturer for failure to provide adequate warnings regarding tooth discoloration from a drug was not preempted by federal regulation of the drug industry since uniform labeling regulation did not prevent a drug manufacturer from adding an additional warning.

In Ferebee v. Chevron Chem. Co., 736 F.2d 1529 (D.C. Cir.), cert. denied, 105 S.Ct. 545 (1984), the defendant claimed that compliance with an EPA-approved and mandated pesticide warning should insulate it from tort liability on an inadequate warning theory. The federal statute provided that a state "shall not impose or continue in effect any requirements for labeling . . . in addition to or different from those required under this subchapter." Id. at 1540. Despite the congressional policy of national uniformity of warnings, the Court of Appeals held that state remedies were not incompatible with the federal program. The opinion noted that "[t]he purposes of [the Act] and those of state tort law may be quite distinct," and that state law may have "broader compensatory goals." Id. The court further held that compliance with both federal and state law is not "impossible" since the manufacturer can continue to use an EPA-approved label and can, at the same time, pay damages to tort plaintiffs or can petition the EPA to allow the labels to be made more comprehensive. Id. at 1542.

This court made no attempt to address the incongruity of its

opinion with these and other similar decisions. This court's broad interpretation of preemption is in complete contradiction to "the long established principles of constitutional interpretation that an exercise by the state of its police power, which would be valid if not superseded by federal action, is superseded only where the repugnance or conflict is so 'direct and positive' that the two acts cannot be fairly reconciled or consistently stand together." Hines v. Davidowitz, 312 U.S. 52, 80 (1941). That is not the case here.

The only thing in this case which conflicts with the purpose of the Act, is the panel's decision which leaves the cigarette manufacturers free to provide inadequate and misleading information concerning the health hazards of cigarettes and to conduct advertising and promotional activities which undermine the effectiveness of the Act's warning and, at the same time, escape tort liability for such action.

CONCLUSION

For the foregoing reasons, the decision of this court is erroneous and a rehearing en banc must be permitted.

BUDD LARNER KENT GROSS PICILLO
ROSENBAUM GREENBERG & SADE
Attorneys for Plaintiff-Petitioner

BY: _____
MARC E. EDELL
A Member of the Firm

Dated: April 21, 1986

DENIAL OF REHEARING AND FOR REHEARING EN BANC BY THE U.S. COURT OF APPEALS FOR THE THIRD CIRCUIT

2025880448

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

Nos. 85-5073 and 85-5074

ANTONIO CIPOLLONE, individually and as Executor of the Estate of Rose D. Cipollone

v.

LIGGETT GROUP, INC., a Delaware Corporation; PHILIP MORRIS INCORPORATED, a Virginia Corporation and LOEW'S THEATRES, INC., a New York Corporation

Liggett Group, Inc., Appellant in 85-5073

Loew's Theatres, Inc., Appellant in 85-5074

SUR PETITION FOR REHEARING

Present: ALDISERT, Chief Judge, SEITZ, GIBBONS, HUNTER, GARTH HIGGINBOTHAM, SLOVITER, BECKER, STAPLETON, and MANSMANN, Circuit Judges

The petition for rehearing filed by

ANTONIO CIPOLLONE

in the above entitled case having been submitted to the judges who participated in the decision of this court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges of the circuit in regular active service not having voted for rehearing by the court in banc, the petition for rehearing is denied.

Judges Gibbons and Mansmann would grant the petition for rehearing.

By the Court,

Clerk

Judge

U.S. COURT OF APPEALS
FOR SIXTH CIRCUIT

2025880450

U.S. COURT OF APPEALS
FOR FIRST CIRCUIT

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PETITION FOR CERTIORARI

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Preemption
Questions and Answers

1. Notwithstanding the ruling by the Third Circuit favorable to tobacco companies, aren't you concerned about the petition by plaintiff's attorney in Cipollone to get the question before the Supreme Court?

The short answer to your question is that we are not unduly concerned. And you should understand there is a lot more to the matter than your question suggests.

In fact, the preemption question was decided in the Third Circuit and sustained on appeal. The question is also before the First and Sixth Circuits and decisions from those courts could be reached within the next several months. Moreover, it would be unusual for the Supreme Court to take the question on certiorari unless there was some novel point of law at issue or the Circuit Courts were divided on the issue. As to division among the Circuits, we'll simply have to wait and see how the First and Sixth Circuits decide. But, in our view, it is unlikely the Supreme Court would get into the matter at this time.

2. What do you think your chances are for the Sixth Circuit to agree with the ruling by the Third Circuit? How about your prospects in the First Circuit?

Obviously, we believe our position is quite strong. The U.S. District Court, in the Roysdon case, ruled in our favor on the question of preemption and the court felt strongly enough to issue a written opinion. We believe the same facts relied on by the District Court will be compelling to the Court of Appeals as well.

The filing of Amicus briefs with the Sixth Circuit are little more than efforts to divert the court from the central issues in this matter. We believe the question of preemption will be decided on its merits and it will sustain the positions we have taken.

As for the First Circuit, we believe our chances are quite good because Congress' intent is so clearly and unequivocally expressed in the Cigarette Labeling and Advertising Act.

SECTION 12 - A STUDY OF NATIONAL EDITORIAL OPINION TOWARD TOBACCO PRODUCT LIABILITY LITIGATION

2025880455

Summary of
a Study of National Editorial Opinion
Toward Tobacco Product Liability Litigation
November 1985 - February 1986

RJR Nabisco, Inc.
March 21, 1986

Introduction

During the period November 1985 to February 1986, considerable media attention was given to product liability litigation. Main objects of attention were two cases, Galbraith versus R.J. Reynolds in California and Roysdon versus R.J. Reynolds in Tennessee. Daily coverage of these cases generated hundreds of millions of print and broadcast impressions and numerous expressions of opinion in editorials and syndicated columns.

From early November 1985 to late February 1986, more than 430 opinion pieces were obtained from clipping services by R.J. Reynolds Industries and then analyzed. The 430 clips were reasonably well distributed geographically and probably reflect a fairly representative sampling of editorial views. The basis for the analysis in this study is a break-out and classification of editorials judged positive, neutral and negative in relation to the litigation, a geographic distribution of those views and an analysis of content to determine dominant themes and their frequency of expression.

The analysis of themes and issues reflected in editorials is considered valuable in three respects. First, a case can be made that editorial opinion is in some degree a reflection of public opinion. Second, and perhaps equally important, is the view that editorials provide insights into the values which underlie expressions of opinion. Third, consideration of the frequency with which themes occur provide insight into the strength of views held and an indication of how widely they are held.

Classification of Editorials

As used in this study, the term "editorial" is used to include both editorials, in the strict sense, and syndicated columns. Both editorials and columns are expressions of opinion usually confined to the editorial pages (as differentiated from the "news" pages) of newspapers.

For classification, editorials were read independently by two coders, who then, using subjective criteria, classified editorials as positive, neutral or negative with respect to supporting R.J. Reynolds' position on cases being litigated. Questionable calls, which were few in number, were discussed and resolved.

The majority (65 percent) of all editorials were classified "positive." Neutral editorials, those not taking a stand one way or the other, accounted for 15 percent and negative editorials made up the remaining 20 percent.

Considering the generally negative views toward smoking and health evident in news stories and editorials prior to November 1985, it was quite surprising that the company's side on the matter of litigation would be taken to the degree reflected in the results. That so many editorials were written is an indication of the widespread concern about the general issue of tobacco product liability. That so many took our side could be taken as fairly strong evidence that the case is not closed against us and when we speak out, our views can be regarded as credible and persuasive.

Why So Many Editorials?

Beginning in early November, R.J. Reynolds actively sought to background the media on tobacco product liability litigation. Hundreds of interviews were given to the print and broadcast media. Specific themes and issues reflecting industries views were repeated over and over by corporate spokespersons. The initial result was more balanced coverage within news columns and on radio and television news programs.

Later, we began to see editorials reflecting our views on product liability, with a few appearing in November and December 1985 followed by hundreds of editorials in January and February 1986. Although this study did not consider editorials appearing after February, they continue to be published, although at a reduced rate.

Analysis

In the four-month period under consideration, 432 editorials were clipped by services to which R.J. Reynolds subscribes. Based on past experience, it is likely that at least four times that many editorials actually appeared. Because of the large number of editorials and their geographic distribution, it is reasonable to generalize from the data produced as follows:

- Interviews by company spokespersons succeeded in crystallizing and perhaps strengthening existing attitudes and opinions favorable to the company. Positive and neutral classifications constituted 80 percent of editorials reviewed. Editorials classified positive numbered 282 or 65 percent. The neutral category accounted for 65 editorials or 15 percent. The remainder, 85 or 20 percent, were classified negative.
- Estimated circulation of editorials in the positive category exceeded 79 million or about 42 percent of the total circulation achieved.
- Neutral circulation was slightly in excess of positive, accounting for 79 million (42 percent).
- Negative circulation was a little over 29 million or slightly less than 16 percent of the total editorial circulation achieved.

Geographic Distribution

Editorials from all over the country were represented in the sample, but may not be an entirely accurate reflection of actual distribution since RJR's clipping services are not geographically representative. However, with that qualification in mind, geographic distribution analysis does provide some useful insights.

For the geographic analysis, the country was divided into six regions: Northeast, Southeast, Upper Midwest, Southwest, Mountain and Far West.

- More editorials appeared in the Southeast (130) than in any other region. The highest percentage of positive editorials (77 percent) appeared in the Upper Midwest, followed by the Southeast (71 percent).
- While positive outnumbered negative in all six regions, the highest number (32) and percentage (29) of negative editorials appeared in the Northeast. The next highest percentage of negative editorials appeared in the Southwest.
- The sample contains only 9 editorials from the Mountain region. For this reason, little or no significance should be attached to percentages even though percentages of editorials by category tracks the overall national results.

Dominant Themes and Issues

Within the categories of positive, neutral and negative, each editorial was analyzed to determine manifest content and then to classify the themes and issues by frequency of appearance. The themes identified are listed in order of frequency under headings of Positive, Neutral and Negative in the table which follows.

Table I

Editorial Themes and Issues in Order of Frequency

Positive	Neutral	Negative
Personal Responsibility	Personal Responsibility	Smoking Health Hazard Proven
Fear of Litigation Flood	Smoking is Addictive	Smoking Is Addictive
Smokers Fairly Warned	Smoking Health Hazard Proven	Tobacco Ads Misleading
Smoking Health Hazard Proven	Fear of Litigation Flood	Fear of Litigation Flood
Smoking Not Addictive	Tobacco Ads Misleading	Personal Responsibility
Freedom of Choice	Right to Advertise	Litigation Inappropriate Solution
Right to Advertise	Economic Effects (Mixed)	Problem of Second Hand Smoke
Smoking Is Addictive	Package Warnings Ineffective	Economic Effects (Negative)
Economic Effects (Positive)	Freedom of Choice	Contributory Negligence
Litigation Inappropriate Solution	Smoking Not Addictive	Exploitation of Smokers

Analysis of Themes/Issues in Editorials Judged Positive

- Personal responsibility for ones own choices was the single most dominant theme accounting for 215 of 906 or 24 percent of total themes addressed.
- Fear of a flood of litigation was the second most dominant theme (166 of 906) accounting for 18 percent of themes addressed.

- The top five themes (personal responsibility, fear of a flood of litigation, smokers fairly warned, health hazard of smoking proven and smoking not addictive) accounted for 720 of 906 themes or 79 percent of all themes addressed.
- Sixteen percent (145 of 906) themes within the editorials judged positive had definite negatives (to the industry) implications. Dominant negative themes within "positive" editorials were that smoking is "addictive" and a proven health hazard.
- Positive economic effects of tobacco and the argument that litigation is an inappropriate solution to the smoking and health questions were the least frequently addressed themes. Together these themes appeared 49 times, or 6 percent of the total.
- Closely linked to the theme of "personal responsibility" was the theme of "freedom of choice." Taken together they accounted for 290 of 906 themes addressed or 32 percent.
- The second most dominant theme, "fear of a flood of litigation" was most often linked to the broader problem of litigation within U.S. society as a whole. The "flood" theme accounted for 166 of 906 or 18 percent of the themes addressed.

Analysis of Themes/Issues in Editorials Judged Neutral

- As with the "positive" category, the single most dominant theme in the neutral editorials was personal responsibility for one's own choices, accounting for 20 percent (35 out of 177) of the themes addressed.
- The second and third most dominant issues addressed in neutral editorials, aggregating 31 percent (55 of 177) of themes addressed were negative. Specific negative themes were smoking is addictive and the case for linking smoking with diseases was proven.
- Three of the top five issues in editorials judged neutral addressed negative themes. On a percentage basis, negative themes outweighed positive by 13 percent (42 percent to 29 percent).
- The top five issues accounted for 126 of 177 themes addressed or 71 percent.

Analysis of Themes/Issues in Editorials Judged Negative

- The dominant theme, the health hazard of smoking, accounted for 24 percent (64 of 259) of themes addressed. Most cited the mounting and overwhelming weight of "evidence" linking smoking as a cause of disease.
- The second and third most dominant themes labeled smoking as addictive and cited manipulative or misleading advertising (including issue ads) as evidence suggesting wrongdoing on the part of cigarette companies. The top three issues accounted for nearly half (48 percent or 128 of 259) of the issues addressed in editorials judged as negative.

- The theme of personal responsibility showed considerable strength even in editorials judged negative. There were 28 references to personal responsibility, accounting for 10 percent of all issues addressed. A typical statement was that, "no one held a gun to anyone's head and made them smoke."
- One theme, asserting that litigation was an inappropriate way to address smoking problems, ranked 6th in frequency in the negative category, 10th in the positive category, but was totally absent from the neutral group

Analysis of Themes Common to Editorials Judged Positive, Neutral and Negative

- There were four themes common to all three categories, which in the aggregate accounted for 790 of 1,342 or 58 percent of all themes addressed. The dominant themes across all categories were personal responsibility (278 of 1,342 or 21 percent), fear of a flood of litigation (216 of 1,342 or 16 percent), hazards of smoking proven (209 of 1,342 or 15 percent), and smoking is addictive (87 of 1,342 or 6 percent).
- Five themes were common to two categories, which accounted for 310 of 1,342 or 23 percent of all themes addressed. The dominant themes common to two categories were smoking not addictive (85 of 1,342 or 6 percent), freedom of choice (85 of 1,342 or 6 percent), right to advertise (48 of 1,342 or 4 percent), ads misleading (48 of 1,342 or 4 percent), and litigation as inappropriate solution (44 of 1,342 or 3 percent).

- Eight themes were confined to a single category aggregating 252 of 1,342 or 19 percent of themes addressed. The most significant of these, smokers fairly warned, accounted for 143 of 1,342 or 11 percent. The remaining seven themes accounted for 8 percent.

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SECTION 13 - OCCUPATIONAL EXPOSURE SITES (OSHA STANDARDS)

Occupational Exposure
Questions and Answers

1. <u>According to studies carried out by Dr. Irving Selikoff, there is a synergistic effect between exposure to asbestos and smoking which multiples the risk of getting lung cancer. Dr. Selikoff's studies show that where the lung cancer risk resulting from exposure to asbestos is 5 and cigarette smoking is 10, the combination of asbestos and cigarette smoking produces a combined lung cancer risk 90 times greater than for the non-exposed non-smoker. Doesn't this give clear indication of cigarette company responsibiltiy for asbestos workers who smoke and later get lung cancer?</u>

   No. In fact there are serious questions concerning the methology used by Dr. Selikoff. For example, comparisons were made between groups which were not comparable, in effect comparing apples and oranges.

2. <u>Even if the risk isn't 90 times as great, shouldn't cigarette companies be liable for their share of responsibility in cases where smoking asbestos workers get lung cancer?</u>

   No, in fact, the alleged interaction between asbestos exposure and cigarette smoking is at best controversial. For example, lung cancer has been consistently produced in biologic experiments in animals exposed to asbestos. However, despite the expenditures of millions of dollars in numerous studies over many years, no one has been able to induce lung cancer in animals as a result of exposure to whole cigarette smoke. While exposure to asbestos clearly can <u>cause</u> lung cancer in experimental animals, exposure to cigarette smoke cannot.

3. <u>Doesn't Dr. Selikoff's work produce a pretty convincing picture of the role of cigarette smoking in greatly increasing the risk of lung cancer in workers exposed to asbestos</u>?

   Dr. Selikoff carried out two studies on the alleged interaction of asbestos exposure and cigarette smoking. The two studies have some rather glaring inconsistencies. In his 1968 study involving 600 subjects, Dr. Selikoff concluded that smokers exposed to asbestos had 90 times the lung cancer risk of non-exposed, non-smokers. In his 1979 study, involving 12,000 subjects, the risk rate for asbestos-exposed smokers was 63, significantly at variance with his earlier study.

Data on this subject is at best controversial. For example, in a February 1986 article in the Journal of Occupational Medicine, Drs. Steenlund and Thun note that "... whenever smoking did modify the effect of occupational exposure (to asbestos, radon and arsenic), the lung cancer ratio was greater for non-smokers (compared to non-exposed non-smokers) than smokers (compared to non-exposed smokers).

4. Isn't it true that people who smoke and who are also exposed to asbestos are at greater risk than people who are only exposed to asbestos?

This is a conclusion that might be drawn from statistics. However, in experimental animal studies, the unerring result of asbestos exposure is lung cancer. In contrast, no animal study involving exposure to whole smoke has ever succeeded in inducing lung cancer.

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